表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）

Hematology
Basophils Absolute(x10E9/L)

| Study Visit | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=215) |
|---|---|---|---|---|---|---|
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Hematology
Eosinophils Absolute(x10E9/L)

| Study Visit | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=215) |
|---|---|---|---|---|---|---|
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Hematology
Lymphocytes Absolute(x10E9/L)

| Study Visit | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=215) |
|---|---|---|---|---|---|---|
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Hematology
Monocytes Absolute(x10E9/L)

| Study Visit | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=215) |
|---|---|---|---|---|---|---|
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Hematology
Neutrophils Absolute(x10E9/L)

| Study Visit | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=215) |
|---|---|---|---|---|---|---|
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Hematology
Basophils(%)

| Study Visit | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=215) |
|---|---|---|---|---|---|---|
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], 1[redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Hematology
Eosinophils(%)

| Study Visit | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=215) |
|---|---|---|---|---|---|---|
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Hematology
Hematocrit(V/V)

| Study Visit | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=215) |
|---|---|---|---|---|---|---|
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Hematology
Hemoglobin(g/L)

| | | TAK-491 | | | | |
|---|---|---|---|---|---|---|
| Study Visit | ロサルタン (n=[redacted]) | 低用量 (n=[redacted]) | 中用量 (n=[redacted]) | 高用量 (n=[redacted]) | 全体 (n=[redacted]) | 全体 (n=215) |
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Hematology
Lymphocytes(%)

| Study Visit | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=215) |
|---|---|---|---|---|---|---|
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Hematology
Ery. Mean Corpuscular Hemoglobin(pg/cell)

| Study Visit | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=215) |
|---|---|---|---|---|---|---|
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Hematology
Ery. Mean Corpuscular HGB Concentration(g/L)

| Study Visit | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=215) |
|---|---|---|---|---|---|---|
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Hematology
Ery. Mean Corpuscular Volume(fL)

| Study Visit | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=215) |
|---|---|---|---|---|---|---|
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Hematology
Monocytes(%)

| Study Visit | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=215) |
|---|---|---|---|---|---|---|
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Hematology
Neutrophils(%)

| | | TAK-491 | | | | |
|---|---|---|---|---|---|---|
| Study Visit | ロサルタン (n=[redacted]) | 低用量 (n=[redacted]) | 中用量 (n=[redacted]) | 高用量 (n=[redacted]) | 全体 (n=[redacted]) | 全体 (n=215) |
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Hematology
Platelets(x10E9/L)

| Study Visit | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=215) |
|---|---|---|---|---|---|---|
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Hematology
Erythrocytes(x10E12/L)

| Study Visit | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=215) |
|---|---|---|---|---|---|---|
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Hematology
Erythrocytes Distribution Width(%)

| Study Visit | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=215) |
|---|---|---|---|---|---|---|
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Hematology
Leukocytes(x10E9/L)

| Study Visit | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=215) |
|---|---|---|---|---|---|---|
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Chemistry
Albumin(g/L)

| Study Visit | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=215) |
|---|---|---|---|---|---|---|
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Chemistry
Alkaline Phosphatase(IU/L)

| | | TAK-491 | | | | |
|---|---|---|---|---|---|---|
| Study Visit | ロサルタン (n=[redacted]) | 低用量 (n=[redacted]) | 中用量 (n=[redacted]) | 高用量 (n=[redacted]) | 全体 (n=[redacted]) | 全体 (n=215) |
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Chemistry
Alanine Aminotransferase(U/L)

| | | TAK-491 | | | | |
|---|---|---|---|---|---|---|
| Study Visit | ロサルタン (n=[redacted]) | 低用量 (n=[redacted]) | 中用量 (n=[redacted]) | 高用量 (n=[redacted]) | 全体 (n=[redacted]) | 全体 (n=215) |
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Chemistry
Aspartate Aminotransferase(U/L)

| Study Visit | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=215) |
|---|---|---|---|---|---|---|
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Chemistry
Bicarbonate(mmol/L)

| Study Visit | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=215) |
|---|---|---|---|---|---|---|
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Chemistry
Direct Bilirubin(umol/L)

| | | TAK-491 | | | | |
|---|---|---|---|---|---|---|
| Study Visit | ロサルタン (n=[redacted]) | 低用量 (n=[redacted]) | 中用量 (n=[redacted]) | 高用量 (n=[redacted]) | 全体 (n=[redacted]) | 全体 (n=215) |
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Chemistry
Bilirubin(umol/L)

| | | TAK-491 | | | | |
|---|---|---|---|---|---|---|
| Study Visit | ロサルタン (n=[redacted]) | 低用量 (n=[redacted]) | 中用量 (n=[redacted]) | 高用量 (n=[redacted]) | 全体 (n=[redacted]) | 全体 (n=215) |
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Chemistry
Calcium(mmol/L)

| Study Visit | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=215) |
|---|---|---|---|---|---|---|
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Chemistry
Creatine Kinase(IU/L)

| | | TAK-491 | | | | |
|---|---|---|---|---|---|---|
| Study Visit | ロサルタン (n=[redacted]) | 低用量 (n=[redacted]) | 中用量 (n=[redacted]) | 高用量 (n=[redacted]) | 全体 (n=[redacted]) | 全体 (n=215) |
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Chemistry
Chloride(mmol/L)

| Study Visit | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=215) |
|---|---|---|---|---|---|---|
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Chemistry
Creatinine(umol/L)

| | | TAK-491 | | | | |
|---|---|---|---|---|---|---|
| Study Visit | ロサルタン (n=[redacted]) | 低用量 (n=[redacted]) | 中用量 (n=[redacted]) | 高用量 (n=[redacted]) | 全体 (n=[redacted]) | 全体 (n=215) |
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Chemistry
eGFR/1.73m$^2$ (Schwartz)(mL/min)

| Study Visit | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=215) |
|---|---|---|---|---|---|---|
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Chemistry
Gamma Glutamyl Transferase(U/L)

| | | TAK-491 | | | | |
|---|---|---|---|---|---|---|
| Study Visit | ロサルタン (n=[redacted]) | 低用量 (n=[redacted]) | 中用量 (n=[redacted]) | 高用量 (n=[redacted]) | 全体 (n=[redacted]) | 全体 (n=215) |
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Chemistry
Glucose(mmol/L)

| Study Visit | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=215) |
|---|---|---|---|---|---|---|
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Chemistry
Potassium(mmol/L)

| Study Visit | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=215) |
|---|---|---|---|---|---|---|
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Chemistry
Phosphate(mmol/L)

| | | TAK-491 | | | | |
|---|---|---|---|---|---|---|
| Study Visit | ロサルタン (n=[redacted]) | 低用量 (n=[redacted]) | 中用量 (n=[redacted]) | 高用量 (n=[redacted]) | 全体 (n=[redacted]) | 全体 (n=215) |
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Chemistry
Protein(g/L)

| Study Visit | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=215) |
|---|---|---|---|---|---|---|
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Chemistry
Sodium(mmol/L)

| | | TAK-491 | | | | |
|---|---|---|---|---|---|---|
| Study Visit | ロサルタン (n=[redacted]) | 低用量 (n=[redacted]) | 中用量 (n=[redacted]) | 高用量 (n=[redacted]) | 全体 (n=[redacted]) | 全体 (n=215) |
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Chemistry
Urea(mmol/L)

| Study Visit | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=215) |
|---|---|---|---|---|---|---|
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Chemistry
Elevated Creatinine(umol/L)

| | | TAK-491 | | | | |
|---|---|---|---|---|---|---|
| | ロサルタン | 低用量 | 中用量 | 高用量 | 全体 | 全体 |
| Study Visit | (n=[redacted]) | (n=[redacted]) | (n=[redacted]) | (n=[redacted]) | (n=[redacted]) | (n=215) |
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Chemistry
Cholesterol(mmol/L)

| Study Visit | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=215) |
|---|---|---|---|---|---|---|
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Chemistry
HDL Cholesterol(mmol/L)

| Study Visit | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=215) |
|---|---|---|---|---|---|---|
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Chemistry
LDL Cholesterol(mmol/L)

| Study Visit | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=215) |
|---|---|---|---|---|---|---|
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | [redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | [redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Chemistry
Triglycerides(mmol/L)

| | | TAK-491 | | | | |
|---|---|---|---|---|---|---|
| Study Visit | ロサルタン (n=[redacted]) | 低用量 (n=[redacted]) | 中用量 (n=[redacted]) | 高用量 (n=[redacted]) | 全体 (n=[redacted]) | 全体 (n=215) |
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Chemistry
Cystatin C(mg/L)

| | | TAK-491 | | | | |
|---|---|---|---|---|---|---|
| Study Visit | ロサルタン (n=[redacted]) | 低用量 (n=[redacted]) | 中用量 (n=[redacted]) | 高用量 (n=[redacted]) | 全体 (n=[redacted]) | 全体 (n=215) |
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-40　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Chemistry
Hemoglobin A1C(%)

| | | TAK-491 | | | | |
|---|---|---|---|---|---|---|
| Study Visit | ロサルタン (n=[redacted]) | 低用量 (n=[redacted]) | 中用量 (n=[redacted]) | 高用量 (n=[redacted]) | 全体 (n=[redacted]) | 全体 (n=215) |
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

ベースライン値は二重盲検期における治験薬初回投与前の最後の測定値とした
総括報告書 Table 14.3.4.1.3.1.1、Table 14.3.4.1.3.2.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）

Hematology

| ロサルタン | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Basophils Absolute(x10E9/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Eosinophils Absolute(x10E9/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Lymphocytes Absolute(x10E9/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Hematology

| ロサルタン | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Monocytes Absolute(x10E9/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Neutrophils Absolute(x10E9/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Basophils(%) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Hematology

| ロサルタン | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Eosinophils(%) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Hematocrit(V/V) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Hemoglobin(g/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Hematology

| ロサルタン | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Lymphocytes(%) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Ery. Mean Corpuscular Hemoglobin(pg/cell) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Ery. Mean Corpuscular HGB Concentration(g/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Hematology

| ロサルタン | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Ery. Mean Corpuscular Volume(fL) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Monocytes(%) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Neutrophils(%) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Hematology

| ロサルタン | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Platelets(x10E9/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Erythrocytes(x10E12/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Erythrocytes Distribution Width(%) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Hematology

| ロサルタン | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Leukocytes(x10E9/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Hematology

| TAK-491 低用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Basophils Absolute(x10E9/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Eosinophils Absolute(x10E9/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Lymphocytes Absolute(x10E9/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Hematology

| TAK-491 低用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Monocytes Absolute(x10E9/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Neutrophils Absolute(x10E9/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Basophils(%) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Hematology

| TAK-491 低用量 | | | Baseline | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Eosinophils(%) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Hematocrit(V/V) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Hemoglobin(g/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Hematology

| TAK-491 低用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Lymphocytes(%) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Ery. Mean Corpuscular Hemoglobin(pg/cell) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Ery. Mean Corpuscular HGB Concentration(g/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Hematology

| TAK-491 低用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Ery. Mean Corpuscular Volume(fL) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Monocytes(%) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Neutrophils(%) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Hematology

| TAK-491 低用量 | | | Baseline | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | Study Visit | Baseline Result | N | Low n (%) | Normal n (%) | High n (%) |
| Platelets(x10E9/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Erythrocytes(x10E12/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Erythrocytes Distribution Width(%) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Hematology

| TAK-491 低用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Leukocytes(x10E9/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Hematology

| TAK-491 中用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Basophils Absolute(x10E9/L) | D1/Visit 4 | Low | | | | |
| | | Normal | | | | |
| | | High | | | | |
| | | Total | | | | |
| | Week 6/Visit 8 | Low | | | | |
| | | Normal | | | | |
| | | High | | | | |
| | | Total | | | | |
| Eosinophils Absolute(x10E9/L) | D1/Visit 4 | Low | | | | |
| | | Normal | | | | |
| | | High | | | | |
| | | Total | | | | |
| | Week 6/Visit 8 | Low | | | | |
| | | Normal | | | | |
| | | High | | | | |
| | | Total | | | | |
| Lymphocytes Absolute(x10E9/L) | D1/Visit 4 | Low | | | | |
| | | Normal | | | | |
| | | High | | | | |
| | | Total | | | | |
| | Week 6/Visit 8 | Low | | | | |
| | | Normal | | | | |
| | | High | | | | |
| | | Total | | | | |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Hematology

| TAK-491 中用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Monocytes Absolute(x10E9/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Neutrophils Absolute(x10E9/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Basophils(%) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Hematology

| TAK-491 中用量 | | | Baseline | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Eosinophils(%) | D1/Visit 4 | Low | | | | |
| | | Normal | | | | |
| | | High | | | | |
| | | Total | | | | |
| | Week 6/Visit 8 | Low | | | | |
| | | Normal | | | | |
| | | High | | | | |
| | | Total | | | | |
| Hematocrit(V/V) | D1/Visit 4 | Low | | | | |
| | | Normal | | | | |
| | | High | | | | |
| | | Total | | | | |
| | Week 6/Visit 8 | Low | | | | |
| | | Normal | | | | |
| | | High | | | | |
| | | Total | | | | |
| Hemoglobin(g/L) | D1/Visit 4 | Low | | | | |
| | | Normal | | | | |
| | | High | | | | |
| | | Total | | | | |
| | Week 6/Visit 8 | Low | | | | |
| | | Normal | | | | |
| | | High | | | | |
| | | Total | | | | |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Hematology

| TAK-491 中用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Lymphocytes(%) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Ery. Mean Corpuscular Hemoglobin(pg/cell) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Ery. Mean Corpuscular HGB Concentration(g/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Hematology

| TAK-491 中用量 | Study Visit | Baseline Result | Baseline N | Post Baseline Results: Low n (%) | Normal n (%) | High n (%) |
|---|---|---|---|---|---|---|
| Ery. Mean Corpuscular Volume(fL) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Monocytes(%) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Neutrophils(%) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Hematology

| TAK-491 中用量 | | | Baseline | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Platelets(x10E9/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | ([redacted]) |
| | | Total | [redacted] | ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Erythrocytes(x10E12/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | ([redacted]) | ([redacted]) |
| | | Total | [redacted] | ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Erythrocytes Distribution Width(%) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Hematology

| TAK-491 中用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Leukocytes(x10E9/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Hematology

| TAK-491 高用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Basophils Absolute(x10E9/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Eosinophils Absolute(x10E9/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Lymphocytes Absolute(x10E9/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Hematology

| TAK-491 高用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Monocytes Absolute(x10E9/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Neutrophils Absolute(x10E9/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Basophils(%) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Hematology

| TAK-491 高用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Eosinophils(%) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Hematocrit(V/V) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Hemoglobin(g/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Hematology

| TAK-491 高用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Lymphocytes(%) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Ery. Mean Corpuscular Hemoglobin(pg/cell) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Ery. Mean Corpuscular HGB Concentration(g/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Hematology

| TAK-491 高用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Ery. Mean Corpuscular Volume(fL) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Monocytes(%) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Neutrophils(%) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Hematology

| TAK-491 高用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Platelets(x10E9/L) | D1/Visit 4 | Low | | | | |
| | | Normal | | | ( ) | |
| | | High | | | | |
| | | Total | | | ( ) | |
| | Week 6/Visit 8 | Low | | | | |
| | | Normal | | | ( ) | |
| | | High | | | | |
| | | Total | | | ( ) | |
| Erythrocytes(x10E12/L) | D1/Visit 4 | Low | | | ( ) | |
| | | Normal | | | ( ) | ( ) |
| | | High | | | | ( ) |
| | | Total | | | ( ) | ( ) |
| | Week 6/Visit 8 | Low | | ( ) | | |
| | | Normal | | | ( ) | |
| | | High | | | ( ) | ( ) |
| | | Total | | ( ) | ( ) | ( ) |
| Erythrocytes Distribution Width(%) | D1/Visit 4 | Low | | | | |
| | | Normal | | | ( ) | ( ) |
| | | High | | | ( ) | ( ) |
| | | Total | | | ( ) | ( ) |
| | Week 6/Visit 8 | Low | | | | |
| | | Normal | | | ( ) | ( ) |
| | | High | | | ( ) | ( ) |
| | | Total | | | ( ) | ( ) |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Hematology

| TAK-491 高用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Leukocytes(x10E9/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Chemistry

| ロサルタン | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Albumin(g/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Alkaline Phosphatase(IU/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Alanine Aminotransferase(U/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Chemistry

| ロサルタン | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Aspartate Aminotransferase(U/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Bicarbonate(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Direct Bilirubin(umol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Chemistry

| ロサルタン | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Bilirubin(umol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Calcium(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Creatine Kinase(IU/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Chemistry

| ロサルタン | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Chloride(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Creatinine(umol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| eGFR/1.73m$^2$ (Schwartz)(mL/min) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Chemistry

| ロサルタン | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Gamma Glutamyl Transferase(U/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Glucose(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Potassium(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Chemistry

| ロサルタン | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Phosphate(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Protein(g/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Sodium(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Chemistry

| ロサルタン | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Urea(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Cholesterol(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| HDL Cholesterol(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Chemistry

| ロサルタン | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| LDL Cholesterol(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Triglycerides(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Cystatin C(mg/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 低用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Albumin(g/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| Alkaline Phosphatase(IU/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Alanine Aminotransferase(U/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 低用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Aspartate Aminotransferase(U/L) | D1/Visit 4 | Low | | | | |
| | | Normal | | | | |
| | | High | | | | |
| | | Total | | | | |
| | Week 6/Visit 8 | Low | | | | |
| | | Normal | | | | |
| | | High | | | | |
| | | Total | | | | |
| Bicarbonate(mmol/L) | D1/Visit 4 | Low | | | | |
| | | Normal | | | | |
| | | High | | | | |
| | | Total | | | | |
| | Week 6/Visit 8 | Low | | | | |
| | | Normal | | | | |
| | | High | | | | |
| | | Total | | | | |
| Direct Bilirubin(umol/L) | D1/Visit 4 | Low | | | | |
| | | Normal | | | | |
| | | High | | | | |
| | | Total | | | | |
| | Week 6/Visit 8 | Low | | | | |
| | | Normal | | | | |
| | | High | | | | |
| | | Total | | | | |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 低用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Bilirubin(umol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Calcium(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Creatine Kinase(IU/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 低用量 | | | Baseline | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Chloride(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Creatinine(umol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| eGFR/1.73m$^2$ (Schwartz)(mL/min) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 低用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Gamma Glutamyl Transferase(U/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Glucose(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Potassium(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 低用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Phosphate(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Protein(g/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Sodium(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 低用量 | | | Baseline | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Urea(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Elevated Creatinine(umol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Cholesterol(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| HDL Cholesterol(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 低用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| LDL Cholesterol(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Triglycerides(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Cystatin C(mg/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 中用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Albumin(g/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Alkaline Phosphatase(IU/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Alanine Aminotransferase(U/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 中用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Aspartate Aminotransferase(U/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Bicarbonate(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Direct Bilirubin(umol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 中用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Bilirubin(umol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Calcium(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Creatine Kinase(IU/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 中用量 | Study Visit | Baseline Result | Baseline N | Post Baseline Results: Low n (%) | Normal n (%) | High n (%) |
|---|---|---|---|---|---|---|
| Chloride(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Creatinine(umol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| eGFR/1.73m$^2$ (Schwartz)(mL/min) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 中用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Gamma Glutamyl Transferase(U/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Glucose(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Potassium(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 中用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Phosphate(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | ([redacted]) | ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | ([redacted]) | ([redacted]) |
| | | Total | [redacted] | ([redacted]) | ([redacted]) | ([redacted]) |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | ([redacted]) | ([redacted]) | ([redacted]) |
| | | High | [redacted] | [redacted] | ([redacted]) | ([redacted]) |
| | | Total | [redacted] | ([redacted]) | ([redacted]) | ([redacted]) |
| Protein(g/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | ([redacted]) | ([redacted]) |
| | | High | [redacted] | [redacted] | ([redacted]) | ([redacted]) |
| | | Total | [redacted] | [redacted] | ([redacted]) | ([redacted]) |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | ([redacted]) | ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] | ([redacted]) |
| | | Total | [redacted] | [redacted] | ([redacted]) | ([redacted]) |
| Sodium(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | ([redacted]) |
| | | Total | [redacted] | [redacted] | ([redacted]) | ([redacted]) |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | ([redacted]) | ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] | ([redacted]) |
| | | Total | [redacted] | [redacted] | ([redacted]) | ([redacted]) |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 中用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Urea(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Cholesterol(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| HDL Cholesterol(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 中用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| LDL Cholesterol(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Triglycerides(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Cystatin C(mg/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 高用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Albumin(g/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Alkaline Phosphatase(IU/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Alanine Aminotransferase(U/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 高用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Aspartate Aminotransferase(U/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Bicarbonate(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 高用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Bilirubin(umol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Calcium(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Creatine Kinase(IU/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 高用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Chloride(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Creatinine(umol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| eGFR/1.73m$^2$ (Schwartz)(mL/min) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 高用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Gamma Glutamyl Transferase(U/L) | D1/Visit 4 | Low | | | | |
| | | Normal | | | | |
| | | High | | | | |
| | | Total | | | | |
| | Week 6/Visit 8 | Low | | | | |
| | | Normal | | | | |
| | | High | | | | |
| | | Total | | | | |
| Glucose(mmol/L) | D1/Visit 4 | Low | | | | |
| | | Normal | | | | |
| | | High | | | | |
| | | Total | | | | |
| | Week 6/Visit 8 | Low | | | | |
| | | Normal | | | | |
| | | High | | | | |
| | | Total | | | | |
| Potassium(mmol/L) | D1/Visit 4 | Low | | | | |
| | | Normal | | | | |
| | | High | | | | |
| | | Total | | | | |
| | Week 6/Visit 8 | Low | | | | |
| | | Normal | | | | |
| | | High | | | | |
| | | Total | | | | |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 高用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Phosphate(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Protein(g/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Sodium(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 高用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Urea(mmol/L) | D1/Visit 4 | Low | | | | |
| | | Normal | | | ( ) | ( ) |
| | | High | | | ( ) | |
| | | Total | | | ( ) | ( ) |
| | Week 6/Visit 8 | Low | | | | |
| | | Normal | | | 5( ) | ( ) |
| | | High | | | | ( ) |
| | | Total | | | ( ) | ( ) |
| Cholesterol(mmol/L) | D1/Visit 4 | Low | | | | |
| | | Normal | | | ( ) | ( ) |
| | | High | | | ( ) | ( ) |
| | | Total | | | ( ) | ( ) |
| | Week 6/Visit 8 | Low | | | | |
| | | Normal | | | ( ) | ( ) |
| | | High | | | ( ) | ( ) |
| | | Total | | | ( ) | ( ) |
| HDL Cholesterol(mmol/L) | D1/Visit 4 | Low | | ( ) | ( ) | |
| | | Normal | | ( ) | ( ) | |
| | | High | | | | |
| | | Total | | ( ) | ( ) | |
| | Week 6/Visit 8 | Low | | ( ) | ( ) | |
| | | Normal | | ( ) | ( ) | |
| | | High | | | | |
| | | Total | | ( ) | ( ) | |

## 表 2.7.4.8-付録-41　血液学的検査及び血液生化学検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 高用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| LDL Cholesterol(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Triglycerides(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Cystatin C(mg/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

ベースライン値は二重盲検期における治験薬初回投与前の最後の測定値とした
総括報告書 Table 14.3.4.1.4.1.1、Table 14.3.4.1.4.2.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-42　尿検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）

Urinalysis
Albumin(mg/L)

| Study Visit | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=215) |
|---|---|---|---|---|---|---|
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-42　尿検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Urinalysis
Albumin/Creatinine(mg/mmol Cr)

| Study Visit | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=215) |
|---|---|---|---|---|---|---|
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-42　尿検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Urinalysis
Creatinine Urine(mmol/L)

| Study Visit | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=215) |
|---|---|---|---|---|---|---|
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-42　尿検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Urinalysis
Urine dipstick pH

| Study Visit | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=215) |
|---|---|---|---|---|---|---|
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | | | | | | |
| Mean | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| (SD) | | | | | | |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | | | | | | |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | | | | | | |
| Mean | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| (SD) | | | | | | |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | | | | | | |
| Change from Baseline | | | | | | |
| N | | | | | | |
| Mean | | | | | | |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | | | | | | |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

## 表 2.7.4.8-付録-42　尿検査の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Urinalysis
Urine dipstick specific gravity

| Study Visit | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=215) |
|---|---|---|---|---|---|---|
| Baseline | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 6/Visit 8 | | | | | | |
| Observed Value | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

ベースライン値は二重盲検期における治験薬初回投与前の最後の測定値とした
総括報告書 Table 14.3.4.1.3.3.1（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-43　尿検査のシフト表（二重盲検期）（AR14.001 試験）

Urinalysis

| ロサルタン | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Albumin(mg/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Albumin/Creatinine(mg/mmol Cr) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Creatinine Urine(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

## 表 2.7.4.8-付録-43　尿検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Urinalysis

| ロサルタン | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Urine dipstick pH | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Urine dipstick specific gravity | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

## 表 2.7.4.8-付録-43　尿検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Urinalysis

| TAK-491 低用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Albumin(mg/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Albumin/Creatinine(mg/mmol Cr) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Creatinine Urine(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-43　尿検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Urinalysis

| TAK-491 低用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Urine dipstick pH | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Urine dipstick specific gravity | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

## 表 2.7.4.8-付録-43　尿検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Urinalysis

| TAK-491 中用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Albumin(mg/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Albumin/Creatinine(mg/mmol Cr) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Creatinine Urine(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

## 表 2.7.4.8-付録-43　尿検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Urinalysis

| TAK-491 中用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Urine dipstick pH | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Urine dipstick specific gravity | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

## 表 2.7.4.8-付録-43　尿検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Urinalysis

| TAK-491 高用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Albumin(mg/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Albumin/Creatinine(mg/mmol Cr) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Creatinine Urine(mmol/L) | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

## 表 2.7.4.8-付録-43　尿検査のシフト表（二重盲検期）（AR14.001 試験）（続き）

Urinalysis

| TAK-491 高用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Urine dipstick pH | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Urine dipstick specific gravity | D1/Visit 4 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 6/Visit 8 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

ベースライン値は二重盲検期における治験薬初回投与前の最後の測定値とした
総括報告書 Table 14.3.4.1.4.3.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）

Hematology
Basophils Absolute(x10E9/L)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Hematology
Eosinophils Absolute(x10E9/L)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Hematology
Lymphocytes Absolute(x10E9/L)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Hematology
Monocytes Absolute(x10E9/L)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Hematology
Neutrophils Absolute(x10E9/L)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Hematology
Basophils(%)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Hematology
Eosinophils(%)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Hematology
Hematocrit(V/V)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Hematology
Hemoglobin(g/L)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Hematology
Lymphocytes(%)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | [redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Hematology
Ery. Mean Corpuscular Hemoglobin(pg/cell)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Hematology
Ery. Mean Corpuscular HGB Concentration(g/L)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Hematology
Ery. Mean Corpuscular Volume(fL)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Hematology
Monocytes(%)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Hematology
Neutrophils(%)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Hematology
Platelets(x10E9/L)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Hematology
Erythrocytes(x10E12/L)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Hematology
Erythrocytes Distribution Width(%)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Hematology
Leukocytes(x10E9/L)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Chemistry
Albumin(g/L)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Chemistry
Alkaline Phosphatase(IU/L)

| | | | TAK-491 | | | | |
|---|---|---|---|---|---|---|---|
| | プラセボ | ロサルタン | 低用量 | 中用量 | 高用量 | 全体 | 全体 |
| Study Visit | (n=[redacted]) | (n=[redacted]) | (n=[redacted]) | (n=[redacted]) | (n=[redacted]) | (n=[redacted]) | (n=[redacted]) |
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Chemistry
Alanine Aminotransferase(U/L)

| | | | TAK-491 | | | | |
|---|---|---|---|---|---|---|---|
| | プラセボ | ロサルタン | 低用量 | 中用量 | 高用量 | 全体 | 全体 |
| Study Visit | (n=[redacted]) | (n=[redacted]) | (n=[redacted]) | (n=[redacted]) | (n=[redacted]) | (n=[redacted]) | (n=[redacted]) |
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Chemistry
Aspartate Aminotransferase(U/L)

| | | | TAK-491 | | | | |
|---|---|---|---|---|---|---|---|
| | プラセボ | ロサルタン | 低用量 | 中用量 | 高用量 | 全体 | 全体 |
| Study Visit | (n=[redacted]) | (n=[redacted]) | (n=[redacted]) | (n=[redacted]) | (n=[redacted]) | (n=[redacted]) | (n=[redacted]) |
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Chemistry
Bicarbonate(mmol/L)

| | | | TAK-491 | | | | |
|---|---|---|---|---|---|---|---|
| | プラセボ | ロサルタン | 低用量 | 中用量 | 高用量 | 全体 | 全体 |
| Study Visit | (n=[redacted]) | (n=[redacted]) | (n=[redacted]) | (n=[redacted]) | (n=[redacted]) | (n=[redacted]) | (n=[redacted]) |
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Chemistry
Direct Bilirubin(umol/L)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Chemistry
Bilirubin(umol/L)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Chemistry
Calcium(mmol/L)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Chemistry
Creatine Kinase(IU/L)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Chemistry
Chloride(mmol/L)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Chemistry
Creatinine(umol/L)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Chemistry
eGFR/1.73m$^2$ (Schwartz)(mL/min)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Chemistry
Gamma Glutamyl Transferase(U/L)

| | | | TAK-491 | | | | |
|---|---|---|---|---|---|---|---|
| | プラセボ | ロサルタン | 低用量 | 中用量 | 高用量 | 全体 | 全体 |
| Study Visit | (n=[redacted]) | (n=[redacted]) | (n=[redacted]) | (n=[redacted]) | (n=[redacted]) | (n=[redacted]) | (n=[redacted]) |
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Chemistry
Glucose(mmol/L)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Chemistry
Potassium(mmol/L)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Chemistry
Phosphate(mmol/L)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Chemistry
Protein(g/L)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Chemistry
Sodium(mmol/L)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Chemistry
Urea(mmol/L)

| | | | TAK-491 | | | | |
|---|---|---|---|---|---|---|---|
| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | 低用量 (n=[redacted]) | 中用量 (n=[redacted]) | 高用量 (n=[redacted]) | 全体 (n=[redacted]) | 全体 (n=[redacted]) |
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Chemistry
Elevated Creatinine(umol/L)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Chemistry
Cholesterol(mmol/L)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | [redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Chemistry
HDL Cholesterol(mmol/L)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Chemistry
LDL Cholesterol(mmol/L)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Chemistry
Triglycerides(mmol/L)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | [redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | [redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Chemistry
Cystatin C(mg/L)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-44　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Chemistry
Hemoglobin A1C(%)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

ベースライン値は中断期における治験薬初回投与前の最後の測定値とした
総括報告書 Table 14.3.4.1.3.1.2、Table 14.3.4.1.3.2.2（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-45　血液学的検査及び血液生化学検査のシフト表（中断期）（AR14.001 試験）

Hematology

| プラセボ | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Basophils Absolute(x10E9/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Eosinophils Absolute(x10E9/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Lymphocytes Absolute(x10E9/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Monocytes Absolute(x10E9/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Neutrophils Absolute(x10E9/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Basophils(%) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Eosinophils(%) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-45　血液学的検査及び血液生化学検査のシフト表（中断期）（AR14.001 試験）（続き）

Hematology

| プラセボ | | | Baseline | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Hematocrit(V/V) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Hemoglobin(g/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Lymphocytes(%) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Ery. Mean Corpuscular Hemoglobin(pg/cell) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Ery. Mean Corpuscular HGB Concentration(g/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Ery. Mean Corpuscular Volume(fL) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Monocytes(%) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-45　血液学的検査及び血液生化学検査のシフト表（中断期）（AR14.001 試験）（続き）

Hematology

| プラセボ | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Neutrophils(%) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Platelets(x10E9/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Erythrocytes(x10E12/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Erythrocytes Distribution Width(%) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Leukocytes(x10E9/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-45　血液学的検査及び血液生化学検査のシフト表（中断期）（AR14.001 試験）（続き）

Hematology

| ロサルタン | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Basophils Absolute(x10E9/L) | Week 8/Visit 9 | Low | | | | |
| | | Normal | | | | |
| | | High | | | | |
| | | Total | | | | |
| Eosinophils Absolute(x10E9/L) | Week 8/Visit 9 | Low | | | | |
| | | Normal | | | | |
| | | High | | | | |
| | | Total | | | | |
| Lymphocytes Absolute(x10E9/L) | Week 8/Visit 9 | Low | | | | |
| | | Normal | | | | |
| | | High | | | | |
| | | Total | | | | |
| Monocytes Absolute(x10E9/L) | Week 8/Visit 9 | Low | | | | |
| | | Normal | | | | |
| | | High | | | | |
| | | Total | | | | |
| Neutrophils Absolute(x10E9/L) | Week 8/Visit 9 | Low | | | | |
| | | Normal | | | | |
| | | High | | | | |
| | | Total | | | | |
| Basophils(%) | Week 8/Visit 9 | Low | | | | |
| | | Normal | | | | |
| | | High | | | | |
| | | Total | | | | |
| Eosinophils(%) | Week 8/Visit 9 | Low | | | | |
| | | Normal | | | | |
| | | High | | | | |
| | | Total | | | | |

表 2.7.4.8-付録-45　血液学的検査及び血液生化学検査のシフト表（中断期）（AR14.001 試験）（続き）

Hematology

| ロサルタン | | | Baseline | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Hematocrit(V/V) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Hemoglobin(g/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Lymphocytes(%) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Ery. Mean Corpuscular Hemoglobin(pg/cell) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Ery. Mean Corpuscular HGB Concentration(g/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Ery. Mean Corpuscular Volume(fL) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Monocytes(%) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-45　血液学的検査及び血液生化学検査のシフト表（中断期）（AR14.001 試験）（続き）

Hematology

| ロサルタン | | | Baseline | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Neutrophils(%) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Platelets(x10E9/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Erythrocytes(x10E12/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Erythrocytes Distribution Width(%) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Leukocytes(x10E9/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-45　血液学的検査及び血液生化学検査のシフト表（中断期）（AR14.001 試験）（続き）

Hematology

| TAK-491 低用量 | | | Baseline | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | Study Visit | Baseline Result | N | Low<br>n (%) | Normal<br>n (%) | High<br>n (%) |
| Basophils Absolute(x10E9/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Eosinophils Absolute(x10E9/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Lymphocytes Absolute(x10E9/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Monocytes Absolute(x10E9/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Neutrophils Absolute(x10E9/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Basophils(%) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Eosinophils(%) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-45　血液学的検査及び血液生化学検査のシフト表（中断期）（AR14.001 試験）（続き）

Hematology

| TAK-491 低用量 | Study Visit | Baseline Result | Baseline N | Post Baseline Results: Low n (%) | Normal n (%) | High n (%) |
|---|---|---|---|---|---|---|
| Hematocrit(V/V) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Hemoglobin(g/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Lymphocytes(%) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Ery. Mean Corpuscular Hemoglobin(pg/cell) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Ery. Mean Corpuscular HGB Concentration(g/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Ery. Mean Corpuscular Volume(fL) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Monocytes(%) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-45　血液学的検査及び血液生化学検査のシフト表（中断期）（AR14.001 試験）（続き）

Hematology

| TAK-491 低用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Neutrophils(%) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Platelets(x10E9/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Erythrocytes(x10E12/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Erythrocytes Distribution Width(%) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Leukocytes(x10E9/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-45　血液学的検査及び血液生化学検査のシフト表（中断期）（AR14.001 試験）（続き）

Hematology

| TAK-491 中用量 | | | Baseline | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | Study Visit | Baseline Result | N | Low n (%) | Normal n (%) | High n (%) |
| Basophils Absolute(x10E9/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Eosinophils Absolute(x10E9/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Lymphocytes Absolute(x10E9/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Monocytes Absolute(x10E9/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Neutrophils Absolute(x10E9/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Basophils(%) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Eosinophils(%) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-45　血液学的検査及び血液生化学検査のシフト表（中断期）（AR14.001 試験）（続き）

Hematology

| TAK-491 中用量 | Study Visit | Baseline Result | Baseline N | Post Baseline Results: Low n (%) | Normal n (%) | High n (%) |
|---|---|---|---|---|---|---|
| Hematocrit(V/V) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Hemoglobin(g/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Lymphocytes(%) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Ery. Mean Corpuscular Hemoglobin(pg/cell) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Ery. Mean Corpuscular HGB Concentration(g/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Ery. Mean Corpuscular Volume(fL) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Monocytes(%) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-45　血液学的検査及び血液生化学検査のシフト表（中断期）（AR14.001 試験）（続き）

Hematology

| TAK-491 中用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Neutrophils(%) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Platelets(x10E9/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Erythrocytes(x10E12/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Erythrocytes Distribution Width(%) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Leukocytes(x10E9/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-45　血液学的検査及び血液生化学検査のシフト表（中断期）（AR14.001 試験）（続き）

Hematology

| TAK-491 高用量 | | | Baseline | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Basophils Absolute(x10E9/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Eosinophils Absolute(x10E9/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Lymphocytes Absolute(x10E9/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Monocytes Absolute(x10E9/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Neutrophils Absolute(x10E9/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Basophils(%) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Eosinophils(%) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-45　血液学的検査及び血液生化学検査のシフト表（中断期）（AR14.001 試験）（続き）

Hematology

| TAK-491 高用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Hematocrit(V/V) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Hemoglobin(g/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Lymphocytes(%) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Ery. Mean Corpuscular Hemoglobin(pg/cell) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Ery. Mean Corpuscular HGB Concentration(g/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Ery. Mean Corpuscular Volume(fL) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Monocytes(%) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-45　血液学的検査及び血液生化学検査のシフト表（中断期）（AR14.001 試験）（続き）

Hematology

| TAK-491 高用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Neutrophils(%) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Platelets(x10E9/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Erythrocytes(x10E12/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Erythrocytes Distribution Width(%) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Leukocytes(x10E9/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-45　血液学的検査及び血液生化学検査のシフト表（中断期）（AR14.001 試験）（続き）

Chemistry

| プラセボ | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Albumin(g/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Alkaline Phosphatase(IU/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Alanine Aminotransferase(U/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Aspartate Aminotransferase(U/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Bicarbonate(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Direct Bilirubin(umol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Bilirubin(umol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-45　血液学的検査及び血液生化学検査のシフト表（中断期）（AR14.001 試験）（続き）

Chemistry

| プラセボ | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Calcium(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Creatine Kinase(IU/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Chloride(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Creatinine(umol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| eGFR/1.73m$^2$ (Schwartz)(mL/min) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Gamma Glutamyl Transferase(U/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Glucose(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-45　血液学的検査及び血液生化学検査のシフト表（中断期）（AR14.001 試験）（続き）

Chemistry

| プラセボ | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Potassium(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Phosphate(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Protein(g/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Sodium(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Urea(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Elevated Creatinine(umol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Cholesterol(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-45　血液学的検査及び血液生化学検査のシフト表（中断期）（AR14.001 試験）（続き）

Chemistry

| プラセボ | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| HDL Cholesterol(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| LDL Cholesterol(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Triglycerides(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Cystatin C(mg/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Hemoglobin A1C(%) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-45　血液学的検査及び血液生化学検査のシフト表（中断期）（AR14.001 試験）（続き）

Chemistry

| ロサルタン | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Albumin(g/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Alkaline Phosphatase(IU/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Alanine Aminotransferase(U/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Aspartate Aminotransferase(U/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Bicarbonate(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Bilirubin(umol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-45　血液学的検査及び血液生化学検査のシフト表（中断期）（AR14.001 試験）（続き）

Chemistry

| ロサルタン | | | Baseline | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Calcium(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Creatine Kinase(IU/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Chloride(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Creatinine(umol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| eGFR/1.73m$^2$ (Schwartz)(mL/min) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Gamma Glutamyl Transferase(U/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Glucose(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-45　血液学的検査及び血液生化学検査のシフト表（中断期）（AR14.001 試験）（続き）

Chemistry

| ロサルタン | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Potassium(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Phosphate(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Protein(g/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Sodium(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Urea(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Cholesterol(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| HDL Cholesterol(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-45　血液学的検査及び血液生化学検査のシフト表（中断期）（AR14.001 試験）（続き）

Chemistry

| ロサルタン | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| LDL Cholesterol(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Triglycerides(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Cystatin C(mg/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-45　血液学的検査及び血液生化学検査のシフト表（中断期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 低用量 | | | Baseline | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Albumin(g/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Alkaline Phosphatase(IU/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Alanine Aminotransferase(U/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Aspartate Aminotransferase(U/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Bicarbonate(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Bilirubin(umol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-45　血液学的検査及び血液生化学検査のシフト表（中断期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 低用量 | | | Baseline | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Calcium(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Creatine Kinase(IU/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Chloride(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Creatinine(umol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| eGFR/1.73m$^2$ (Schwartz)(mL/min) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Gamma Glutamyl Transferase(U/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Glucose(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-45　血液学的検査及び血液生化学検査のシフト表（中断期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 低用量 | | | Baseline | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Potassium(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Phosphate(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Protein(g/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Sodium(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Urea(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Cholesterol(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| HDL Cholesterol(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-45　血液学的検査及び血液生化学検査のシフト表（中断期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 低用量 | | | Baseline | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| LDL Cholesterol(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Triglycerides(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Cystatin C(mg/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-45　血液学的検査及び血液生化学検査のシフト表（中断期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 中用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Albumin(g/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Alkaline Phosphatase(IU/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Alanine Aminotransferase(U/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Aspartate Aminotransferase(U/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Bicarbonate(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Direct Bilirubin(umol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Bilirubin(umol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-45　血液学的検査及び血液生化学検査のシフト表（中断期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 中用量 | | | Baseline | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Calcium(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Creatine Kinase(IU/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Chloride(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Creatinine(umol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| eGFR/1.73m$^2$ (Schwartz)(mL/min) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Gamma Glutamyl Transferase(U/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Glucose(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-45　血液学的検査及び血液生化学検査のシフト表（中断期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 中用量 | | | Baseline | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Potassium(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Phosphate(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Protein(g/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Sodium(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Urea(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Elevated Creatinine(umol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Cholesterol(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-45　血液学的検査及び血液生化学検査のシフト表（中断期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 中用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| HDL Cholesterol(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| LDL Cholesterol(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Triglycerides(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Cystatin C(mg/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-45　血液学的検査及び血液生化学検査のシフト表（中断期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 高用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Albumin(g/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Alkaline Phosphatase(IU/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Alanine Aminotransferase(U/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Aspartate Aminotransferase(U/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Bicarbonate(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Bilirubin(umol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-45　血液学的検査及び血液生化学検査のシフト表（中断期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 高用量 | | | Baseline | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Calcium(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Creatine Kinase(IU/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Chloride(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Creatinine(umol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| eGFR/1.73m$^2$ (Schwartz)(mL/min) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Gamma Glutamyl Transferase(U/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Glucose(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-45　血液学的検査及び血液生化学検査のシフト表（中断期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 高用量 | | | Baseline | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Potassium(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Phosphate(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Protein(g/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Sodium(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Urea(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Cholesterol(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| HDL Cholesterol(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

## 表 2.7.4.8-付録-45　血液学的検査及び血液生化学検査のシフト表（中断期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 高用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| LDL Cholesterol(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Triglycerides(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Cystatin C(mg/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

ベースライン値は中断期における治験薬初回投与前の最後の測定値とした
総括報告書 Table 14.3.4.1.4.1.2、Table 14.3.4.1.4.2.2（5.3.5.1-3）から引用

表 2.7.4.8-付録-46　尿検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）

Urinalysis
Albumin(mg/L)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-46　尿検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Urinalysis
Albumin/Creatinine(mg/mmol Cr)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-46　尿検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Urinalysis
Creatinine Urine(mmol/L)

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-46　尿検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Urinalysis
Urine dipstick pH

| | | | TAK-491 | | | | |
|---|---|---|---|---|---|---|---|
| | プラセボ | ロサルタン | 低用量 | 中用量 | 高用量 | 全体 | 全体 |
| Study Visit | (n=[redacted]) | (n=[redacted]) | (n=[redacted]) | (n=[redacted]) | (n=[redacted]) | (n=[redacted]) | (n=[redacted]) |
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

## 表 2.7.4.8-付録-46　尿検査の要約統計量及びベースラインからの変化量（中断期）（AR14.001 試験）（続き）

Urinalysis
Urine dipstick specific gravity

| Study Visit | プラセボ (n=[redacted]) | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|---|---|---|---|
| Baseline | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 8/Visit 9 | | | | | | | |
| Observed Value | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| (SD) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

ベースライン値は中断期における治験薬初回投与前の最後の測定値とした
総括報告書 Table 14.3.4.1.3.3.2（5.3.5.1-3）から引用

## 表 2.7.4.8-付録-47　尿検査のシフト表（中断期）（AR14.001 試験）

Urinalysis

| プラセボ | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Albumin(mg/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Albumin/Creatinine(mg/mmol Cr) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Creatinine Urine(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Urine dipstick pH | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Urine dipstick specific gravity | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-47　尿検査のシフト表（中断期）（AR14.001 試験）（続き）

Urinalysis

| ロサルタン | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Albumin(mg/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Albumin/Creatinine(mg/mmol Cr) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Creatinine Urine(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Urine dipstick pH | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Urine dipstick specific gravity | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-47　尿検査のシフト表（中断期）（AR14.001 試験）（続き）

Urinalysis

| TAK-491 低用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Albumin(mg/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Albumin/Creatinine(mg/mmol Cr) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Creatinine Urine(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Urine dipstick pH | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Urine dipstick specific gravity | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-47　尿検査のシフト表（中断期）（AR14.001 試験）（続き）

Urinalysis

| TAK-491 中用量 | | | Baseline | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Albumin(mg/L) | Week 8/Visit 9 | Low | | | | |
| | | Normal | | | ( ) | |
| | | High | | | | |
| | | Total | | | ( ) | |
| Albumin/Creatinine(mg/mmol Cr) | Week 8/Visit 9 | Low | | | | |
| | | Normal | | | ( ) | ( ) |
| | | High | | | ( ) | ( ) |
| | | Total | | | ( ) | ( ) |
| Creatinine Urine(mmol/L) | Week 8/Visit 9 | Low | | | | |
| | | Normal | | | ( ) | |
| | | High | | | | |
| | | Total | | | ( ) | |
| Urine dipstick pH | Week 8/Visit 9 | Low | | | | |
| | | Normal | | | ( ) | |
| | | High | | | | |
| | | Total | | | ( ) | |
| Urine dipstick specific gravity | Week 8/Visit 9 | Low | | | | |
| | | Normal | | | ( ) | |
| | | High | | | | |
| | | Total | | | ( ) | |

## 表 2.7.4.8-付録-47　尿検査のシフト表（中断期）（AR14.001 試験）（続き）

Urinalysis

| TAK-491 高用量 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Albumin(mg/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| Albumin/Creatinine(mg/mmol Cr) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Creatinine Urine(mmol/L) | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| Urine dipstick pH | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| Urine dipstick specific gravity | Week 8/Visit 9 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |

ベースライン値は中断期における治験薬初回投与前の最後の測定値とした

総括報告書 Table 14.3.4.1.4.3.2（5.3.5.1-3）から引用

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）

Hematology
Basophils Absolute(x10E9/L)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Hematology
Eosinophils Absolute(x10E9/L)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Hematology
Lymphocytes Absolute(x10E9/L)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Hematology
Monocytes Absolute(x10E9/L)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Hematology
Neutrophils Absolute(x10E9/L)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-48　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Hematology
Atypical lymphocytes Absolute(x10E9/L)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Hematology
Basophils(%)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Hematology
Eosinophils(%)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Hematology
Hematocrit(V/V)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Hematology
Hemoglobin(g/L)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Hematology
Lymphocytes(%)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-48　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Hematology
Lymphocytes Atypical(%)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | ([redacted]) | ([redacted]) | ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Hematology
Ery. Mean Corpuscular Hemoglobin(pg/cell)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Hematology
Ery. Mean Corpuscular HGB Concentration(g/L)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Hematology
Ery. Mean Corpuscular Volume(fL)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Hematology
Monocytes(%)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Hematology
Neutrophils(%)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Hematology
Platelets(x10E9/L)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Hematology
Erythrocytes(x10E12/L)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Hematology
Erythrocytes Distribution Width(%)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Hematology
Leukocytes(x10E9/L)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Chemistry
Albumin(g/L)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Chemistry
Alkaline Phosphatase(IU/L)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Chemistry
Alanine Aminotransferase(U/L)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Chemistry
Aspartate Aminotransferase(U/L)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Chemistry
Bicarbonate(mmol/L)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Chemistry
Direct Bilirubin(umol/L)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Chemistry
Bilirubin(umol/L)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Chemistry
Calcium(mmol/L)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Chemistry
Creatine Kinase(IU/L)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Chemistry
Chloride(mmol/L)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Chemistry
Creatinine(umol/L)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Chemistry
eGFR/1.73m$^2$ (Schwartz)(mL/min)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Chemistry
Gamma Glutamyl Transferase(U/L)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Chemistry
Glucose(mmol/L)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Chemistry
Potassium(mmol/L)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Chemistry
Phosphate(mmol/L)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Chemistry
Protein(g/L)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-48　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Chemistry
Sodium(mmol/L)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Chemistry
Urea(mmol/L)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Chemistry
Elevated Creatinine(umol/L)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Chemistry
Cholesterol(mmol/L)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Chemistry
HDL Cholesterol(mmol/L)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Chemistry
LDL Cholesterol(mmol/L)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Chemistry
Triglycerides(mmol/L)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-48 血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Chemistry
Cystatin C(mg/L)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-48　血液学的検査及び血液生化学検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Chemistry
Hemoglobin A1C(%)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | - | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |

ベースライン値は二重盲検期における治験薬初回投与前の最後の測定値とした
総括報告書　補遺 Table 14.3.4.1.3.1.3、Table 14.3.4.1.3.2.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-49　血液学的検査及び血液生化学検査のシフト表（長期非盲検期）（AR14.001 試験）

Hematology

| TAK-491 単独 | Study Visit | Baseline Result | Baseline N | Post Baseline Results Low n (%) | Normal n (%) | High n (%) |
|---|---|---|---|---|---|---|
| Basophils Absolute(x10E9/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Eosinophils Absolute(x10E9/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Lymphocytes Absolute(x10E9/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-49　血液学的検査及び血液生化学検査のシフト表（長期非盲検期）（AR14.001 試験）（続き）

Hematology

| TAK-491 単独 | Study Visit | Baseline Result | Baseline N | Post Baseline Results: Low n (%) | Normal n (%) | High n (%) |
|---|---|---|---|---|---|---|
| Monocytes Absolute(x10E9/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Neutrophils Absolute(x10E9/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Basophils(%) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-49　血液学的検査及び血液生化学検査のシフト表（長期非盲検期）（AR14.001 試験）（続き）

Hematology

| TAK-491 単独 | Study Visit | Baseline Result | Baseline N | Post Baseline Results: Low n (%) | Normal n (%) | High n (%) |
|---|---|---|---|---|---|---|
| Eosinophils(%) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Hematocrit(V/V) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Hemoglobin(g/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-49　血液学的検査及び血液生化学検査のシフト表（長期非盲検期）（AR14.001 試験）（続き）

Hematology

| TAK-491 単独 | Study Visit | Baseline Result | Baseline N | Post Baseline Results: Low n (%) | Normal n (%) | High n (%) |
|---|---|---|---|---|---|---|
| Lymphocytes(%) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Ery. Mean Corpuscular Hemoglobin(pg/cell) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Ery. Mean Corpuscular HGB Concentration(g/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-49　血液学的検査及び血液生化学検査のシフト表（長期非盲検期）（AR14.001 試験）（続き）

Hematology

| TAK-491 単独 | Study Visit | Baseline Result | Baseline N | Post Baseline Results: Low n (%) | Normal n (%) | High n (%) |
|---|---|---|---|---|---|---|
| Ery. Mean Corpuscular Volume(fL) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Monocytes(%) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Neutrophils(%) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-49　血液学的検査及び血液生化学検査のシフト表（長期非盲検期）（AR14.001 試験）（続き）

Hematology

| TAK-491 単独 | Study Visit | Baseline Result | Baseline N | Post Baseline Results Low n (%) | Normal n (%) | High n (%) |
|---|---|---|---|---|---|---|
| Platelets(x10E9/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Erythrocytes(x10E12/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Erythrocytes Distribution Width(%) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-49　血液学的検査及び血液生化学検査のシフト表（長期非盲検期）（AR14.001 試験）（続き）

Hematology

| TAK-491 単独 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Leukocytes(x10E9/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-49　血液学的検査及び血液生化学検査のシフト表（長期非盲検期）（AR14.001 試験）（続き）

Hematology

| TAK-491 と他の降圧薬の併用 | Study Visit | Baseline Result | Baseline N | Post Baseline Results Low n (%) | Normal n (%) | High n (%) |
|---|---|---|---|---|---|---|
| Basophils Absolute(x10E9/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Eosinophils Absolute(x10E9/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Lymphocytes Absolute(x10E9/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-49　血液学的検査及び血液生化学検査のシフト表（長期非盲検期）（AR14.001 試験）（続き）

Hematology

| TAK-491 と他の降圧薬の併用 | Study Visit | Baseline Result | Baseline N | Post Baseline Results: Low n (%) | Normal n (%) | High n (%) |
|---|---|---|---|---|---|---|
| Monocytes Absolute(x10E9/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Neutrophils Absolute(x10E9/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Basophils(%) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-49　血液学的検査及び血液生化学検査のシフト表（長期非盲検期）（AR14.001 試験）（続き）

Hematology

| TAK-491 と他の降圧薬の併用 | Study Visit | Baseline Result | Baseline N | Post Baseline Results Low n (%) | Normal n (%) | High n (%) |
|---|---|---|---|---|---|---|
| Eosinophils(%) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Hematocrit(V/V) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | Normal | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | Normal | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Hemoglobin(g/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | Normal | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | Total | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | | Normal | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | Total | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | | Normal | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | Total | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |

表 2.7.4.8-付録-49　血液学的検査及び血液生化学検査のシフト表（長期非盲検期）（AR14.001 試験）（続き）

Hematology

| TAK-491 と他の降圧薬の併用 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Lymphocytes(%) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Ery. Mean Corpuscular Hemoglobin(pg/cell) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Ery. Mean Corpuscular HGB Concentration(g/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-49　血液学的検査及び血液生化学検査のシフト表（長期非盲検期）（AR14.001 試験）（続き）

Hematology

| TAK-491 と他の降圧薬の併用 | Study Visit | Baseline Result | Baseline N | Post Baseline Results Low n (%) | Normal n (%) | High n (%) |
|---|---|---|---|---|---|---|
| Ery. Mean Corpuscular Volume(fL) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Monocytes(%) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Neutrophils(%) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-49　血液学的検査及び血液生化学検査のシフト表（長期非盲検期）（AR14.001 試験）（続き）

Hematology

| TAK-491 と他の降圧薬の併用 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Platelets(x10E9/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| Erythrocytes(x10E12/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Erythrocytes Distribution Width(%) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |

表 2.7.4.8-付録-49　血液学的検査及び血液生化学検査のシフト表（長期非盲検期）（AR14.001 試験）（続き）

Hematology

| TAK-491 と他の降圧薬の併用 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Leukocytes(x10E9/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-49　血液学的検査及び血液生化学検査のシフト表（長期非盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 単独 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Albumin(g/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Alkaline Phosphatase(IU/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Alanine Aminotransferase(U/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-49　血液学的検査及び血液生化学検査のシフト表（長期非盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 単独 | Study Visit | Baseline Result | Baseline N | Post Baseline Results: Low n (%) | Normal n (%) | High n (%) |
|---|---|---|---|---|---|---|
| Aspartate Aminotransferase(U/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Bicarbonate(mmol/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Direct Bilirubin(umol/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-49　血液学的検査及び血液生化学検査のシフト表（長期非盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 単独 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Bilirubin(umol/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Calcium(mmol/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Creatine Kinase(IU/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-49　血液学的検査及び血液生化学検査のシフト表（長期非盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 単独 | Study Visit | Baseline Result | Baseline N | Post Baseline Results Low n (%) | Normal n (%) | High n (%) |
|---|---|---|---|---|---|---|
| Chloride(mmol/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Creatinine(umol/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| eGFR/1.73m$^2$ (Schwartz)(mL/min) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-49　血液学的検査及び血液生化学検査のシフト表（長期非盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 単独 | Study Visit | Baseline Result | Baseline N | Post Baseline Results Low n (%) | Normal n (%) | High n (%) |
|---|---|---|---|---|---|---|
| Gamma Glutamyl Transferase(U/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Glucose(mmol/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Potassium(mmol/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-49　血液学的検査及び血液生化学検査のシフト表（長期非盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 単独 | Study Visit | Baseline Result | Baseline N | Post Baseline Results: Low n (%) | Normal n (%) | High n (%) |
|---|---|---|---|---|---|---|
| Phosphate(mmol/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Protein(g/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Sodium(mmol/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-49　血液学的検査及び血液生化学検査のシフト表（長期非盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 単独 | Study Visit | Baseline Result | Baseline N | Post Baseline Results Low n (%) | Normal n (%) | High n (%) |
|---|---|---|---|---|---|---|
| Urea(mmol/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Cholesterol(mmol/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| HDL Cholesterol(mmol/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | | Normal | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | | Normal | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | | Normal | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |

表 2.7.4.8-付録-49　血液学的検査及び血液生化学検査のシフト表（長期非盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 単独 | Study Visit | Baseline Result | Baseline N | Post Baseline Results: Low n (%) | Normal n (%) | High n (%) |
|---|---|---|---|---|---|---|
| LDL Cholesterol(mmol/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Triglycerides(mmol/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Cystatin C(mg/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-49　血液学的検査及び血液生化学検査のシフト表（長期非盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 単独 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Hemoglobin A1C(%) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | ([redacted]) |
| | | Total | [redacted] | [redacted] | ([redacted]) | ([redacted]) |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | ([redacted]) |
| | | Total | [redacted] | [redacted] | ([redacted]) | ([redacted]) |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | ([redacted]) |
| | | Total | [redacted] | [redacted] | ([redacted]) | ([redacted]) |

表 2.7.4.8-付録-49　血液学的検査及び血液生化学検査のシフト表（長期非盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 と他の降圧薬の併用 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Albumin(g/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| Alkaline Phosphatase(IU/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Alanine Aminotransferase(U/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |

表 2.7.4.8-付録-49　血液学的検査及び血液生化学検査のシフト表（長期非盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 と他の降圧薬の併用 | Study Visit | Baseline Result | Baseline N | Post Baseline Results Low n (%) | Normal n (%) | High n (%) |
|---|---|---|---|---|---|---|
| Aspartate Aminotransferase(U/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Bicarbonate(mmol/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | | Normal | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | | Normal | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | | Normal | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| Direct Bilirubin(umol/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] ([redacted]) |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |

表 2.7.4.8-付録-49　血液学的検査及び血液生化学検査のシフト表（長期非盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 と他の降圧薬の併用 | Study Visit | Baseline Result | Baseline N | Post Baseline Results Low n (%) | Normal n (%) | High n (%) |
|---|---|---|---|---|---|---|
| Bilirubin(umol/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| Calcium(mmol/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Creatine Kinase(IU/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |

表 2.7.4.8-付録-49　血液学的検査及び血液生化学検査のシフト表（長期非盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 と他の降圧薬の併用 | | | | Post Baseline Results | | |
|---|---|---|---|---|---|---|
| | | | Baseline | Low | Normal | High |
| | Study Visit | Baseline Result | N | n (%) | n (%) | n (%) |
| Chloride(mmol/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| Creatinine(umol/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | | Normal | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| eGFR/1.73m$^2$ (Schwartz)(mL/min) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] ([redacted]) | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] ([redacted]) | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] ([redacted]) | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |

表 2.7.4.8-付録-49　血液学的検査及び血液生化学検査のシフト表（長期非盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 と他の降圧薬の併用 | Study Visit | Baseline Result | Baseline N | Post Baseline Results Low n (%) | Normal n (%) | High n (%) |
|---|---|---|---|---|---|---|
| Gamma Glutamyl Transferase(U/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Glucose(mmol/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | Normal | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | Total | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] ([redacted]) | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | Total | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Potassium(mmol/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] ([redacted]) | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | Total | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] ([redacted]) | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | Total | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] ([redacted]) | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | Total | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |

表 2.7.4.8-付録-49　血液学的検査及び血液生化学検査のシフト表（長期非盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 と他の降圧薬の併用 | Study Visit | Baseline Result | Baseline N | Post Baseline Results Low n (%) | Normal n (%) | High n (%) |
|---|---|---|---|---|---|---|
| Phosphate(mmol/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Protein(g/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Sodium(mmol/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |

表 2.7.4.8-付録-49　血液学的検査及び血液生化学検査のシフト表（長期非盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 と他の降圧薬の併用 | Study Visit | Baseline Result | Baseline N | Post Baseline Results Low n (%) | Normal n (%) | High n (%) |
|---|---|---|---|---|---|---|
| Urea(mmol/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Cholesterol(mmol/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| HDL Cholesterol(mmol/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

## 表 2.7.4.8-付録-49　血液学的検査及び血液生化学検査のシフト表（長期非盲検期）（AR14.001 試験）（続き）

Chemistry

| TAK-491 と他の降圧薬の併用 | Study Visit | Baseline Result | Baseline N | Post Baseline Results Low n (%) | Normal n (%) | High n (%) |
|---|---|---|---|---|---|---|
| LDL Cholesterol(mmol/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Triglycerides(mmol/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Cystatin C(mg/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

ベースライン値は二重盲検期における治験薬初回投与前の最後の測定値とした
総括報告書　補遺 Table 14.3.4.1.4.1.3、Table 14.3.4.1.4.2.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-50 尿検査の要約統計量及びベースラインからの変化量（長期非盲検期）
（AR14.001 試験）

Urinalysis
Albumin(mg/L)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-50 尿検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Urinalysis
Albumin/Creatinine(mg/mmol Cr)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-50 尿検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Urinalysis
Creatinine Urine(mmol/L)

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-50 尿検査の要約統計量及びベースラインからの変化量（長期非盲検期）（AR14.001 試験）（続き）

Urinalysis
Urine dipstick pH

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] ([redacted]) | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted], [redacted] | [redacted], [redacted] | [redacted], [redacted] |

表 2.7.4.8-付録-50　尿検査の要約統計量及びベースラインからの変化量（長期非盲検期）
（AR14.001 試験）（続き）

Urinalysis
Urine dipstick specific gravity

| Study Visit | TAK-491 単独 (n=[redacted]) | TAK-491 と他の降圧薬の併用 (n=[redacted]) | 全体 (n=[redacted]) |
|---|---|---|---|
| Baseline | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 11 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week [redacted]/Visit 13 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Week 52/Visit 16 | | | |
| Observed Value | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | |
| N | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] |

ベースライン値は二重盲検期における治験薬初回投与前の最後の測定値とした
総括報告書　補遺 Table 14.3.4.1.3.3.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-51　尿検査のシフト表（長期非盲検期）（AR14.001 試験）

Urinalysis

| TAK-491 単独 | Study Visit | Baseline Result | Baseline N | Post Baseline Results: Low n (%) | Normal n (%) | High n (%) |
|---|---|---|---|---|---|---|
| Albumin(mg/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Albumin/Creatinine(mg/mmol Cr) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Creatinine Urine(mmol/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-51　尿検査のシフト表（長期非盲検期）（AR14.001 試験）（続き）

Urinalysis

| TAK-491 単独 | Study Visit | Baseline Result | Baseline N | Post Baseline Results: Low n (%) | Normal n (%) | High n (%) |
|---|---|---|---|---|---|---|
| Urine dipstick pH | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| Urine dipstick specific gravity | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-51 尿検査のシフト表（長期非盲検期）（AR14.001 試験）（続き）

Urinalysis

| TAK-491 と他の降圧薬の併用 | Study Visit | Baseline Result | Baseline N | Post Baseline Results Low n (%) | Normal n (%) | High n (%) |
|---|---|---|---|---|---|---|
| Albumin(mg/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| Albumin/Creatinine(mg/mmol Cr) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| Creatinine Urine(mmol/L) | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |

表 2.7.4.8-付録-51　尿検査のシフト表（長期非盲検期）（AR14.001 試験）（続き）

Urinalysis

| TAK-491 と他の降圧薬の併用 | Study Visit | Baseline Result | Baseline N | Post Baseline Results: Low n (%) | Normal n (%) | High n (%) |
|---|---|---|---|---|---|---|
| Urine dipstick pH | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| Urine dipstick specific gravity | Week [redacted]/Visit 11 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | Week [redacted]/Visit 13 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] ([redacted]) |
| | Week 52/Visit 16 | Low | [redacted] | [redacted] | [redacted] | [redacted] |
| | | Normal | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | High | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |
| | | Total | [redacted] | [redacted] | [redacted] ([redacted]) | [redacted] |

ベースライン値は二重盲検期における治験薬初回投与前の最後の測定値とした
総括報告書　補遺 Table 14.3.4.1.4.3.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-52　バイタルサイン（立位脈拍数）の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）

Vital Signs Parameter
Standing Pulse Rate (beats/min)

| Study Visit | ロサルタン (n=[redacted]) | TAK-491 低用量 (n=[redacted]) | TAK-491 中用量 (n=[redacted]) | TAK-491 高用量 (n=[redacted]) | TAK-491 全体 (n=[redacted]) | 全体 (n=215) |
|---|---|---|---|---|---|---|
| Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Week [redacted] | | | | | | |
| Observed | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Week [redacted] | | | | | | |
| Observed | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted]1) | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

表 2.7.4.8-付録-52　バイタルサイン（立位脈拍数）の要約統計量及びベースラインからの変化量（二重盲検期）（AR14.001 試験）（続き）

Vital Signs Parameter
Standing Pulse Rate (beats/min)

| | | TAK-491 | | | | |
|---|---|---|---|---|---|---|
| Study Visit | ロサルタン (n=[redacted]) | 低用量 (n=[redacted]) | 中用量 (n=[redacted]) | 高用量 (n=[redacted]) | 全体 (n=[redacted]) | 全体 (n=215) |
| Week 6 - 1D | | | | | | |
| Observed | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Week 6 | | | | | | |
| Observed | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Change from Baseline | | | | | | |
| N | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Mean (SD) | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Median | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Min, Max | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

ベースライン値は二重盲検期における治験薬初回投与前の最後の測定値とした
Week 6 - 1D：ABPM 機器の装着 Visit
総括報告書 Table 14.3.4.2.1.1（5.3.5.1-3）から引用