SUPPLEMENTARY MATERIAL

TITLE
Long-term safety and effectiveness of adalimumab in Japanese patients with non-infectious intermediate, posterior, or panuveitis: postmarketing surveillance of 251 patients

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Table S1  Adverse drug reactions by SOC (safety analysis set)*

| SOC | Any ADR | Serious ADR |
|-----|---------|-------------|
|     | No. of pts | (%) | No. of pts | (%) |
|     | N = 251 |     | N = 251 |     |
| All | 47     | (18.7) | 14 | (5.6) |
| Infections and infestations | 21 | (8.4) | 8 | (3.2) |
| Herpes zoster | 5 | (2.0) | 2 | (0.8) |
| Tuberculosisb | 4 | (1.6) | 4 | (1.6) |
| Nasopharyngitis | 2 | (0.8) | 0 | (0.0) |
| Pneumonia bacterial | 1 | (0.4) | 1 | (0.4) |
| Pyelonephritis | 1 | (0.4) | 1 | (0.4) |
| Cellulitis | 1 | (0.4) | 0 | (0.0) |
| Fungal infection | 1 | (0.4) | 0 | (0.0) |
| Otitis media acute | 1 | (0.4) | 0 | (0.0) |
| Pharyngitis | 1 | (0.4) | 0 | (0.0) |
| Pneumonia | 1 | (0.4) | 0 | (0.0) |
| Urethritis | 1 | (0.4) | 0 | (0.0) |
| Tinea versicolor | 1 | (0.4) | 0 | (0.0) |
| Oral herpes | 1 | (0.4) | 0 | (0.0) |
| Skin and subcutaneous tissue disorders | 10 | (4.0) | 2 | (0.8) |
| Drug eruption | 2 | (0.8) | 1 | (0.4) |
| Rash | 2 | (0.8) | 0 | (0.0) |
| Urticaria | 2 | (0.8) | 0 | (0.0) |
| Dermatitis | 1 | (0.4) | 1 | (0.4) |
| Toxic skin eruption | 1 | (0.4) | 1 | (0.4) |
| Erythema | 1 | (0.4) | 0 | (0.0) |
| Pruritus | 1 | (0.4) | 0 | (0.0) |
| Dermatitis psoriasiform | 1 | (0.4) | 0 | (0.0) |
| General disorders and administration site conditions | 8 | (3.2) | 0 | (0.0) |
| Injection site erythema | 2 | (0.8) | 0 | (0.0) |
| Injection site reaction | 2 | (0.8) | 0 | (0.0) |
| Injection site pruritus | 1 | (0.4) | 0 | (0.0) |
| Injection site rash | 1 | (0.4) | 0 | (0.0) |
| Pain | 1 | (0.4) | 0 | (0.0) |
| Pyrexia | 1 | (0.4) | 0 | (0.0) |
| Administration site erythema | 1 | (0.4) | 0 | (0.0) |
| Investigations | 7 | (2.8) | 0 | (0.0) |
| Alanine aminotransferase increased | 3 | (1.2) | 0 | (0.0) |
| Aspartate aminotransferase increased | 3 | (1.2) | 0 | (0.0) |
| C-reactive protein increased | 1 | (0.4) | 0 | (0.0) |
| Eosinophil count increased | 1 | (0.4) | 0 | (0.0) |
| Red blood cell sedimentation rate increased | 1 | (0.4) | 0 | (0.0) |
| Blood beta-D-glucan increased | 1 | (0.4) | 0 | (0.0) |
| Cell marker increased | 1 | (0.4) | 0 | (0.0) |
| Respiratory, thoracic and mediastinal disorders | 4 | (1.6) | 1 | (0.4) |
| Upper respiratory tract inflammation | 2 | (0.8) | 0 | (0.0) |
| Interstitial lung disease | 1 | (0.4) | 1 | (0.4) |
| Oropharyngeal pain | 1 | (0.4) | 0 | (0.0) |
| Eye disorders | 3 | (1.2) | 0 | (0.0) |
| Blepharitis | 1 | (0.4) | 0 | (0.0) |
| Chalazion | 1 | (0.4) | 0 | (0.0) |
| Vitreous opacities | 1 | (0.4) | 0 | (0.0) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 2 | (0.8) | 2 | (0.8) |
| SOC PT | Any ADR | Serious ADR |
|--------|---------|-------------|
|        | No. of pts | (%)     | No. of pts | (%)     |
| Colon cancer | 1 (0.4) | 1 (0.4) |
| Breast cancer  | 1 (0.4) | 1 (0.4) |
| Nervous system disorders | 2 (0.8) | 1 (0.4) |
| Putaminal hemorrhage | 1 (0.4) | 1 (0.4) |
| Post-herpetic neuralgia | 1 (0.4) | 0 (0.0) |
| Gastrointestinal disorders | 2 (0.8) | 0 (0.0) |
| Gastrointestinal disorder | 1 (0.4) | 0 (0.0) |
| Nausea | 1 (0.4) | 0 (0.0) |
| Musculoskeletal and connective tissue disorders | 2 (0.8) | 1 (0.4) |
| Polymyalgia rheumatica | 1 (0.4) | 1 (0.4) |
| Arthralgia | 1 (0.4) | 0 (0.0) |
| Psychiatric disorders | 1 (0.4) | 1 (0.4) |
| Personality change | 1 (0.4) | 1 (0.4) |

ADR adverse drug reaction, PT preferred term, SOC system organ class

* Medical Dictionary for Regulatory Activities/Japanese version 23.0

*b Includes tuberculosis (n = 2), disseminated tuberculosis (n = 1), and tuberculoma of central nervous system (n = 1)
### Table S2  Adverse drug reactions by the three major primary diseases of uveitis (safety analysis set)\(^a\)

| SOC PT | Sarcoïdosis | Vogt-Koyanagi-Harada disease | Behcet's disease |
|--------|-------------|------------------------------|-----------------|
|        | Any ADR | Serious ADR | Any ADR | Serious ADR | Any ADR | Serious ADR |
|        | No. of pts | (%) | No. of pts | (%) | No. of pts | (%) | No. of pts | (%) |
| Total | 8 | (27.6) | 4 | (13.8) | 12 | (18.8) | 3 | (4.7) | 11 | (15.9) | 2 | (2.9) |
| Infections and infestations | 3 | (10.3) | 1 | (3.4) | 4 | (6.3) | 2 | (3.1) | 5 | (7.2) | 1 | (1.4) |
| Herpes zoster | 1 | (3.4) | 1 | (3.4) | 1 | (1.6) | 0 | (0) | 3 | (4.3) | 1 | (1.4) |
| Nasopharyngitis | 1 | (3.4) | 0 | (0) | 0 | (0) | 0 | (0) | 0 | (0) | 0 | (0) |
| Urethritis | 1 | (3.4) | 0 | (0) | 0 | (0) | 0 | (0) | 0 | (0) | 0 | (0) |
| Cellulitis | 0 | (0) | 0 | (0) | 1 | (1.6) | 0 | (0) | 0 | (0) | 0 | (0) |
| Disseminated tuberculosis | 0 | (0) | 0 | (0) | 1 | (1.6) | 1 | (1.6) | 0 | (0) | 0 | (0) |
| Tuberculosis | 0 | (0) | 0 | (0) | 1 | (1.6) | 1 | (1.6) | 0 | (0) | 0 | (0) |
| Otitis media acute | 0 | (0) | 0 | (0) | 0 | (0) | 0 | (0) | 1 | (1.4) | 0 | (0) |
| Oral herpes | 0 | (0) | 0 | (0) | 0 | (0) | 0 | (0) | 1 | (1.4) | 0 | (0) |
| Neoplasms benign, malignant and unspecified (including cysts and polyps) | 1 | (3.4) | 1 | (3.4) | 1 | (1.6) | 1 | (1.6) | 0 | (0) | 0 | (0) |
| Colon cancer | 1 | (3.4) | 1 | (3.4) | 0 | (0) | - | - | 0 | (0) | 0 | (0) |
| Breast cancer female | 0 | (0) | 0 | (0) | 1 | (1.6) | 1 | (1.6) | 0 | (0) | 0 | (0) |
| Nervous system disorders | 0 | (0) | 0 | (0) | 1 | (1.6) | 0 | (0) | 0 | (0) | 0 | (0) |
| Post-herpetic neuralgia | 0 | (0) | 0 | (0) | 1 | (1.6) | 0 | (0) | 0 | (0) | 0 | (0) |
| Eye disorders | 1 | (3.4) | 0 | (0) | 1 | (1.6) | 0 | (0) | 0 | (0) | 0 | (0) |
| Vitreous opacities | 1 | (3.4) | 0 | (0) | 0 | (0) | - | - | 0 | (0) | 0 | (0) |
| Chalazion | 0 | (0) | 0 | (0) | 1 | (1.6) | 0 | (0) | 0 | (0) | 0 | (0) |
| Gastrointestinal disorders | 0 | (0) | 0 | (0) | 2 | (3.1) | 0 | (0) | 0 | (0) | 0 | (0) |
| Gastrointestinal disorder | 0 | (0) | 0 | (0) | 1 | (1.6) | 0 | (0) | 0 | (0) | 0 | (0) |
| Nausea | 0 | (0) | 0 | (0) | 1 | (1.6) | 0 | (0) | 0 | (0) | 0 | (0) |
| Skin and subcutaneous tissue disorders | 1 | (3.4) | 1 | (3.4) | 3 | (4.7) | 0 | (0) | 4 | (5.8) | 1 | (1.4) |
| Toxic skin eruption | 1 | (3.4) | 1 | (3.4) | 0 | (0) | 0 | (0) | 0 | (0) | 0 | (0) |
| Drug eruption | 0 | (0) | 0 | (0) | 1 | (1.6) | 0 | (0) | 1 | (1.4) | 1 | (1.4) |
| Erythema | 0 | (0) | 0 | (0) | 1 | (1.6) | 0 | (0) | 0 | (0) | 0 | (0) |
| Rash | 0 | (0) | 0 | (0) | 1 | (1.6) | 0 | (0) | 1 | (1.4) | 0 | (0) |
| Dermatitis | 0 | (0) | 0 | (0) | 0 | (0) | 0 | (0) | 0 | (0) | 0 | (0) |
| Pruritus | 0 | (0) | 0 | (0) | 0 | (0) | 0 | (0) | 1 | (1.4) | 0 | (0) |
| Dermatitis psoriasisiform | 0 | (0) | 0 | (0) | 0 | (0) | 0 | (0) | 1 | (1.4) | 0 | (0) |
| Musculoskeletal and connective tissue | 1 | (3.4) | 1 | (3.4) | 1 | (1.6) | 0 | (0) | 0 | (0) | 0 | (0) |
| Polymyalgia rheumatica | 1 | (3.4) | 1 | (3.4) | 0 | (0) | 0 | (0) | 0 | (0) | 0 | (0) |
| Arthralgia | 0 | (0) | 0 | (0) | 1 | (1.6) | 0 | (0) | 0 | (0) | 0 | (0) |
| General disorders and administration site conditions | 0 | (0) | 0 | (0) | 2 | (3.1) | 0 | (0) | 2 | (2.9) | 0 | (0) |
| SOC PT                   | Sarcoidosis |                      | Vogt-Koyanagi-Harada disease |                      | Behçet's disease |                      |
|-------------------------|-------------|----------------------|-------------------------------|----------------------|-----------------|----------------------|
|                         | Any ADR     | Serious ADR          | Any ADR                       | Serious ADR          | Any ADR         | Serious ADR          |
|                         | No. of pts  | (%)                  | No. of pts                    | (%)                  | No. of pts      | (%)                  |
|                         | N = 29      |                      | N = 29                        |                      | N = 64          |                      |
| Pain                    | 0           | (0)                  | 1                             | (1.6)                | 0               | (0)                  |
| Administration site erythema | 0           | (0)                  | 1                             | (1.6)                | 0               | (0)                  |
| Injection site rash     | 0           | (0)                  | 0                             | (0)                  | 0               | (0)                  |
| Injection site reaction | 0           | (0)                  | 0                             | (0)                  | 0               | (0)                  |
| Investigations          | 2           | (6.9)                | 1                             | (1.6)                | 0               | (0)                  |
| Alanine aminotransferase increased | 1           | (3.4)                | 1                             | (1.6)                | 0               | (0)                  |
| Aspartate aminotransferase increased | 1           | (3.4)                | 1                             | (1.6)                | 0               | (0)                  |
| Eosinophil count increased | 1           | (3.4)                | 0                             | (0)                  | 0               | (0)                  |
| Cell marker increased   | 0           | (0)                  | 0                             | (0)                  | 1               | (1.4)                |

ADR adverse drug reaction, PT preferred term, SOC system organ class

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