

Retreatment with telaprevir combination therapy in hepatitis C patients with well-characterized prior treatment response.

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Table 3. Adverse Events Leading to Discontinuation and Most Common Adverse Events Reported According to Treatment Group

| | T12PR24 | T12PR48 | Unassigned* | Total |
|---|----------------|----------------|--------------------|----------------|
| n (%) | N = 81 | N = 34 | N = 2 | N = 117 |
| Adverse events leading to discontinuation** | 5 (6) | 3 (9) | 2 (100) | 10 (9) |
| Rash events‡ | 4 (5) | 1 (3) | 1 (50) | 6 (5) |
| Pruritus | 1 (1) | 0 (0) | 1 (50) | 2 (2) |
| Pyrexia | 1 (1) | 1 (3) | 0 (0) | 2 (2) |
| Anemia | 2 (2) | 0 (0) | 0 (0) | 2 (2) |
| Adverse events occurring in >10% of patients, n (%) | | | | |
| Severe adverse event | 12 (15) | 7 (21) | 1 (50) | 20 (17) |
| General disorder | | | | |
| Fatigue | 30 (37) | 21 (62) | 1 (50) | 52 (44) |
| Influenza-like illness | 17 (21) | 10 (29) | 1 (50) | 28 (24) |
| Pyrexia | 16 (20) | 6 (18) | 0 (0) | 22 (19) |
| Chills | 11 (14) | 4 (12) | 0 (0) | 15 (13) |
| Asthenia | 9 (11) | 3 (9) | 0 (0) | 12 (10) |
| Gastrointestinal disorder | | | | |
| Nausea | 20 (25) | 11 (32) | 1 (50) | 32 (27) |
| Diarrhea | 19 (24) | 6 (18) | 0 (0) | 25 (21) |
| Hemorrhoids | 9 (11) | 4 (12) | 0 (0) | 13 (11) |
| Skin and subcutaneous disorders | | | | |
| Pruritus | 34 (42) | 9 (26) | 2 (100) | 45 (38) |
| Rash† | 23 (28) | 13 (38) | 1 (50) | 37 (32) |
| Dry skin | 10 (12) | 5 (15) | 0 (0) | 15 (13) |
| Nervous system disorders | | | | |
| Headache | 23 (28) | 14 (41) | 0 (0) | 37 (32) |
| Psychiatric disorders | | | | |
| Insomnia | 14 (17) | 7 (21) | 1 (50) | 22 (19) |
| Depression | 9 (11) | 4 (12) | 0 (0) | 13 (11) |
| Musculoskeletal disorders | | | | |
| Myalgia | 10 (12) | 5 (15) | 0 (0) | 15 (13) |
| Arthralgia | 11 (14) | 2 (6) | 0 (0) | 13 (11) |
| Respiratory disorders | | | | |
| Cough | 9 (11) | 4 (12) | 2 (100) | 15 (13) |
| Blood and lymphatic disorders | | | | |
| Anemia | 22 (27) | 7 (21) | 0 (0) | 29 (25) |

*Unassigned patients discontinued treatment prior to week 12 assignment of treatment duration.

**Adverse events leading to discontinuation in ≥ 2 patients.

‡This category includes all patients experiencing rash events as assessed with the use of a group of related terms to identify all dermatologic events. All treatment discontinuations due to rash happened during telaprevir phase.

†Using a variety of descriptive terms to identify all dermatologic events, rash events occurred in 44%, 53%, 100%, and 48% of T12PR24, T12PR48, Unassigned, and Total patients, respectively.