Abrocitinib Summary of Clinical Safety (Atopic Dermatitis)

Proportion and Incidence Rates for Treatment-Emergent Adverse Events - Short-Term Safety Pool

| | | Placebo (N=454) | Abrocitinib 100mg QD (N=719) | Abrocitinib 200mg QD (N=698) | All Abrocitinib (N=1417) |
|---|------------------------|---------------------------------|------------------------------------|------------------------------------|----------------------------------|
| Subjects with adverse events | n (%¹) | 244 (53.8) | 431 (60.1) | 468 (66.9) | 899 (63.4) |
| | IR (95% CI)¹ | 335.26 (293.57, 381.55) | 414.20 (375.52, 456.20) | 499.80 (455.43, 547.53) | 450.83 (421.72, 481.50) |
| Subjects with serious adverse events | n (%¹) | 14 (3.1) | 18 (2.5) | 12 (1.7) | 30 (2.1) |
| | IR (95% CI)¹ | 12.44 (6.70, 21.43) | 9.69 (5.73, 15.47) | 6.52 (3.36, 11.57) | 8.11 (5.47, 11.65) |
| Subjects with severe adverse events | n (%¹) | 25 (5.7) | 28 (4.0) | 20 (2.9) | 48 (3.4) |
| | IR (95% CI)¹ | 23.92 (15.30, 35.82) | 15.74 (10.43, 22.89) | 11.03 (6.72, 17.19) | 13.30 (9.79, 17.70) |
| Subjects discontinued from study due to adverse events [1] | n (%¹) | 35 (7.8) | 36 (5.2) | 35 (5.1) | 71 (5.1) |
| | IR (95% CI)¹ | 33.06 (22.78, 46.63) | 20.65 (14.44, 28.74) | 19.49 (13.57, 27.25) | 19.96 (15.58, 25.24) |
| Subjects discontinued study drug due to AE and continue study [2] | n (%¹) | 4 (0.9) | 6 (0.8) | 2 (0.3) | 8 (0.6) |
| | IR (95% CI)¹ | 3.62 (0.96, 9.79) | 3.11 (1.14, 6.98) | 1.22 (0.14, 4.56) | 2.14 (0.92, 4.31) |
| Subjects with dose reduced or temporary discontinuation due to adverse events | n (%¹) IR (95% CI)¹ | 16 (3.6) 14.45 (8.15, 24.01) | 32 (4.4) 17.58 (12.01, 24.96) | 31 (4.4) 17.34 (11.77, 24.77) | 63 (4.4) 17.44 (13.39, 22.39) |

Includes Studies: B7451006, B7451012, B7451013, B7451029, B7451036

Includes data up to the end of risk period (the smaller of [last dose date, death date] for B7451012/13/36 subjects who enrolled into the LTE study; or the smaller of [last dose date prior to Week 16 dose date/visit date, death date] for B7451029 subjects with available Week 16 dose date/visit date; otherwise, the smaller of [last dose date + 28 days, death date]).

n: Number of subjects with the event. Incidence Rates: Number of subjects with events per 100 patient-years.

Confidence intervals (CI) were calculated for incidence rates based on the assumption that the actual count of cases arises from a Poisson distribution for treatment groups with zero event; otherwise they were based on gamma distribution weighted by study-size.

¹Study-size adjusted results.

Serious Adverse Events - according to the investigator's assessment.

Two subjects (B7451029 1346 13469002, B7451029 1247 12479010) had an AE that started before Week 16 and discontinued due to that AE after Week 16. Those AEs were also included in this table.

- [1] Subjects who had an AE record that indicated that the AE caused the subject to be discontinued from the study.
- [2] Subjects who had an AE record that indicated that action taken with study treatment was drug withdrawn but AE did not cause the subject to be discontinued from study.

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