DOP008

SAFETY OF ADALIMUMAB IN CHILDREN AND ADOLESCENTS WITH MODERATE TO SEVERE CROHN'S DISEASE: INTERIM RESULTS OF THE CAPE REGISTRY

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Introduction

- Safety and efficacy of Humira (adalimumab) in children and adolescents with moderately to severely active Crohn's disease (CD) has been demonstrated in the IMAgINE 1 and 2 trials[1,2]
- The long-term safety profile of Humira was consistent with AE incidence proportions and rates in adult and pediatric CD trials[2,3]
- CAPE is a post-marketing, 10-year, non-interventional, multinational registry assessing the long-term safety and effectiveness of Humira as used in routine clinical practice in children and adolescents with moderately to severely active CD
    - Patients being prescribed and treated with immunomodulators (IMM) are being enrolled as a reference group
- The registry is currently enrolling
- Interim safety data are presented through the data cut-off date of 31 May 2017

[1]Hyams JS, et al. *Gastroenterology* 2012;143:365-374.
[2]Faubion WA, et al. *Inflamm Bowel Dis* 2017;23(3):453-460.
[3]Colombel JF, et al. *Inflamm Bowel Dis* 2009;15:1308-1319.

Methods

- Patients who enrolled in the registry are being followed for up to 10 years
- Inclusion criteria:
  - Patients between the ages of 6 and 17 years inclusive
  - Newly prescribed or already receiving Humira OR
  - Treated with IMM therapy (azathioprine, mercaptopurine, or methotrexate) for ≥12 weeks prior to enrollment and with no concurrent use of a biologic at enrollment
- Adverse events (AEs) are reported for all patients who received ≥1 dose of Humira (Humira Registry Group) or ≥1 dose of IMM without concurrent biologic (IMM Registry Group) during the registry
- Treatment-emergent AEs are defined as those occurring from the first dose in the registry up to 70 days (for Humira) or 30 days (for IMM) after the last dose in the registry or up to the cut-off date

Results

- 909 patients were enrolled and dosed in the registry as of 31 May 2017
  — 518 patients assigned to Humira Registry Group; 391 patients assigned to IMM Registry Group
- Mean ± SD exposure to Humira in the registry: 267.1 ± 174.2 days in the Humira Registry Group
- Mean ± SD exposure to IMM in the registry: 306.6 ± 197.55 days in the IMM Registry Group

Baseline Demographics and Characteristics	IMM Registry Group N=391	Humira Registry Group N=518
Sex; male, n (%)	235 (60.1)	297 (57.3)
Race; white, n (%)	357 (91.5)	454 (87.6)
Age; years, mean ± SD	13.8 ± 2.66	14.4 ± 2.41
Weight; kg, mean ± SD	49.53 ± 14.904	51.20 ± 15.663
CD duration at baseline; years, mean ± SD	2.6 ± 2.60	2.9 ± 2.34
shPCDAI, mean ± SD	7.26 ± 11.587	10.65 ± 15.218
Discontinuation from Registry, n (%)*	15 (3.8)	13 (2.5)
Adverse event	0	0
Withdrew consent	1 (0.3)	2 (0.4)
Lost to follow-up	0	1 (0.2)
Lack of effectiveness	0	0
Other	14 (3.6)	10 (1.9)

*No patient discontinued due to adverse event, lack of effectiveness, or remission/good clinical status.

Registry Treatment-Emergent Adverse Events

	CAPE Registry				IMAgINE 1 & 2*
	IMM Registry Group N=391, 328.2 PY		Humira Registry Group N=518, 378.8 PY		Adalimumab N=192, 498.1 PY
	n (%)	Events (E/100PY)	n (%)	Events (E/100PY)	Events (E/100PY)
Any AE	41 (10.5)	92 (28.0)	59 (11.4)	129 (34.1)	2899 (582.0)
Serious AE	28 (7.2)	62 (18.9)	37 (7.1)	82 (21.6)	164 (32.9)
AE leading to discontinuation†	0	0	1 (0.2)	1 (0.3)	78 (15.7)
Infection	17 (4.3)	22 (6.7)	22 (4.2)	30 (7.9)	677 (135.9)
Serious Infection	9 (2.3)	10 (3.0)	13 (2.5)	17 (4.5)	33 (6.6)
Opportunistic Infection (excl. oral candidiasis and tuberculosis)	0	0	0	0	11 (2.2)
Any Malignancy	0	0	0	0	0
Hematologic-related AE	0	0	1 (0.2)	1 (0.3)	39 (7.8)
Intestinal stricture	3 (0.8)	5 (1.5)	5 (1.0)	5 (1.3)	6 (1.2)
Worsening/onset of psoriasis	0	0	3 (0.6)	3 (0.8)	7 (1.4)
AE leading to death	0	0	0	0	0

*Faubion WA, et al. Inflamm Bowel Dis 2017;23(3):453-460 and AbbVie data on file.

†CAPE registry: discontinuation from registry; IMAgINE 1 & 2 trials: discontinuation from study drug.

Conclusions

- The safety of Humira observed in CAPE was comparable to its known benefit risk profile in children and adolescents with moderately to severely active CD[1,2]
- No new safety signals were identified
- Longer observation periods are needed to ascertain a more accurate risk of uncommon AEs

[1]Hyams JS, et al. *Gastroenterology* 2012;143:365-374.
[2]Faubion WA, et al. *Inflamm Bowel Dis* 2017;23(3):453-460.