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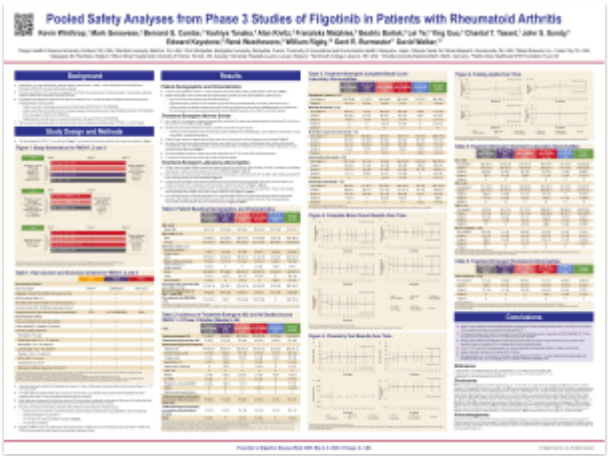
AGA

POOLED SAFETY ANALYSES FROM PHASE 3 STUDIES OF FILGOTINIB IN PATIENTS WITH RHEUMATOID ARTHRITIS



Inflammatory Bowel Diseases
IBD: Adverse Events Related to Therapy
Presented on Sunday, May 3, 2020 12:30 PM

Author(s): Beatrix Bartok[7], Kevin L. Winthrop[2], Mark Genovese[3], Bernard G. Combe[4], Yoshiya Tanaka[5], Alan Kivitz[6], Franziska Matzkies[7], Lei Ye[7], Ying Guo[7], Chantal T. Tasset[1], John S. Sundy[7], Edward Keystone[8], Rene Westhovens[9], William Rigby[10], Gerd R. Burmester[11], David R. Walker[12]

Background: Filgotinib (FIL) is an oral, selective Janus Kinase 1 inhibitor under development for the treatment of rheumatoid arthritis (RA) and other inflammatory diseases. Safety and efficacy of FIL was investigated in the FINCH clinical program, which includes three Phase 3, randomised, multicentre studies in patients with moderate to severely active RA. FINCH1: patients with inadequate response to MTX (NCT02889796); FINCH2: patients receiving conventional synthetic disease-modifying antirheumatic drugs (csDMARDs) with inadequate response to biological DMARDs (NCT02873936); FINCH3: MTX-naïve patients initiating MTX ± FIL, or receiving FIL monotherapy (NCT02886728). We present pooled safety data up to 24 weeks (W24).

Methods: The FINCH studies enrolled patients with RA (2010 ACR/EULAR criteria), ≥6 swollen joints and ≥6 tender joints at screening and Day 1. Safety analyses included patients receiving ≥1 dose of study drug. Patients in FINCH 1 and 2 who did not experience at least a 20% improvement in both swollen joint count and tender joint count by W14 discontinued study drug and switched to standard of care. W24 safety data from all studies were aggregated and summarised. Key safety endpoints were treatment-emergent adverse events (TEAEs), serious TEAEs, TEAEs of interest, deaths and treatment-emergent laboratory abnormalities.

Results: 3452 patients were evaluated; 2088 received FIL. At W24, the frequency of TEAEs and TEAEs of interest were similar for those who received FIL and those in the control groups (Table 1). Most TEAEs were infections. Laboratory abnormality rates were similar between FIL and control groups, and were mild to moderate (grades 1 and 2). Overall, the frequency of major adverse cardiac events, herpes zoster virus, deep vein thrombosis and pulmonary embolism was low, and similar across groups.

Conclusion: Pooled data from this large database highlights the favourable safety and tolerability profile of FIL in patients with RA both as monotherapy and in combination with MTX/csDMARD.

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Table 1. Frequency of treatment-emergent AEs and all deaths across FINCH 1–3 Phase 3 studies (Day 1 – Week 24)

n (%)	Placebo + MTX/csDMARD N = 1,039	ADA 40mg + MTX N = 325	FIL 100 mg + MTX/csDMARD N = 840	FIL 200 mg + MTX/csDMARD N = 1,038	FIL 200 mg N = 210	FIL Total N = 2,088
Treatment-emergent AE	614 (59.1)	185 (56.9)	527 (62.7)	663 (63.9)	113 (53.8)	1303 (62.4)
Treatment-emergent serious AE	37 (3.6)	14 (4.3)	37 (4.4)	44 (4.2)	10 (4.8)	91 (4.4)
Treatment-emergent AE of Interest	253 (24.4)	91 (28.0)	232 (27.6)	289 (27.8)	54 (25.7)	575 (27.5)
Infectious AE	244 (23.5)	88 (27.1)	229 (27.3)	283 (27.3)	53 (25.2)	565 (27.1)
Serious Infectious AE	10 (1.0)	8 (2.5)	13 (1.5)	13 (1.3)	3 (1.4)	29 (1.4)
Herpes Zoster	4 (0.4)	2 (0.6)	5 (0.6)	6 (0.6)	1 (0.5)	12 (0.6)
Hepatitis B or C	1 (<0.1)	1 (0.3)	0	2 (0.2)	0	2 (<0.1)
Opportunistic Infections	0	1 (0.3)	0	1 (<0.1)	0	1 (<0.1)
Active TB	0	0	0	0	0	0
MACE	5 (0.5)	1 (0.3)	2 (0.2)	2 (0.2)	1 (0.5)	5 (0.2)
DVT/PE	3 (0.3)	0	0	1 (<0.1)*	0	1 (<0.1)*
Malignancy Excluding NMSC	4 (0.4)	1 (0.3)	1 (0.1)	0	0	1 (<0.1)
NMSC	0	0	0	1 (<0.1)	0	1 (<0.1)
Gastrointestinal Perforations	0	0	0	0	0	0
Death	2 (0.2)	0	1 (0.1)	3 (0.3)	0	4 (0.2)

ADA, adalimumab; csDMARD, conventional synthetic DMARD; DVT, deep vein thrombosis; FIL, filgotinib; MACE, major adverse cardiac event; NMSC, Nonmelanoma Skin Cancer; PBO, placebo; PE, pulmonary embolism; TB, tuberculosis. # excludes one event of retinal vein occlusion.

Disclosure: B. Bartok: No Conflicts; K. L. Winthrop: AbbVie: Consulting; Bristol-Myers Squibb Company: Consulting; Gilead Sciences: Consulting; Insmed Incorporated: Consulting; Pfizer: Consulting; Roche: Consulting; UCB Pharma: Grant/Research Support; M. Genovese: Abbvie: Consulting; Gilead: Consulting; Lilly: Consulting; B. G. Combe: AbbVie: Grant/Research Support; Bristol-Myers Squibb: Grant/Research Support; Eli Lilly & Co.: Grant/Research Support; Gilead Sciences: Grant/Research Support; Janssen: Grant/Research Support; MSD: Grant/Research Support; Novartis: Grant/Research Support; Pfizer: Grant/Research Support; Roche-Chugai: Grant/Research Support; Sanofi: Grant/Research Support; UCB: Grant/Research Support; Y. Tanaka: AbbVie Inc: Grant/Research Support; Eli Lilly and Company: Grant/Research Support; Galapagos NV: Consulting; Gilead: Grant/Research Support; Pfizer: Consulting; A. Kivitz: AbbVie: Advisory Committees or Review Panels; Celgene: Speaking and Teaching; Horizon: Speaking and Teaching; Janssen: Advisory Committees or Review Panels; Merck, Novartis: Speaking and Teaching; Pfizer Pharmaceuticals, Genzyme, Sanofi, Regeneron, Flexion, AbbVie: Speaking and Teaching; Pfizer Pharmaceuticals, Sanofi, Gilead, Amgen, GSK: Stock Shareholder; Pfizer Pharmaceuticals, Sanofi, Regeneron, SUN Pharma Advanced Research: Consulting; Pfizer Pharmaceuticals, UCB, Regeneron Genzyme, Sanofi, Boehringer Ingeleheim: Advisory Committees or Review Panels; F. Matzkies: Gilead Sciences: Employment; L. Ye: Gilead: Employment; Y. Guo: Gilead Sciences: Employment; C. T. Tasset: Galapagos: Employment, Employment; J. S. Sundy: Gilead Sciences: Employment, Stock Shareholder; E. Keystone: AbbVie: Grant/Research Support, Speaking and Teaching; AbbVie, Amgen, AstraZeneca Pharma, Bristol-Myers Squibb Company, Celltrion: Consulting; Amgen: Grant/Research Support, Speaking and Teaching; Bristol-Myers Squibb: Speaking and Teaching; F. Hoffmann-La Roche Inc.: Speaking and Teaching; Gilead Sciences: Grant/Research Support; Janssen Inc.: Speaking and Teaching; Lilly Pharmaceuticals: Grant/Research Support; Lilly Pharmaceuticals, Merck, Pfizer Pharmaceuticals: Consulting; Merck: Grant/Research Support, Speaking and Teaching; Myriad Autoimmune, F. Hoffmann-La Roche Inc, Genentech Inc, Gilead, Janssen Inc: Consulting; Pfizer Pharmaceuticals: Grant/Research Support, Speaking and Teaching; PuraPharm: Grant/Research Support; Sandoz, Sanofi-Genzyme, Samsung Bioepsis: Consulting; Sanofi: Grant/Research Support; Sanofi Genzyme: Speaking and Teaching; UCB: Speaking and Teaching; R. Westhovens: No Conflicts; W. Rigby: Gilead: Consulting; G. R. Burmester: Abbvie: Consulting; Gilead: Speaking and Teaching; Lilly: Consulting; Pfizer: Speaking and Teaching; D. R. Walker: lilly: Grant/Research Support; Novartis: Grant/Research Support; Pfizer: Grant/Research Support; Roche: Consulting;