Table 1. The dynamics of the disease activity during treatment with TOFA

Parameters	Weeks	All patients (n=138)	Had prior biologic use history (group 1) (n=51)	Biologic naive (group 2) (n=87)
DAS28	baseline	5.5 (4.6-6.2)	5.1 (4.5-5.9)	5.7 (4.8-6.5)\$
	week 12	4.2 (3.1-4.8)*	3.9 (2.8-4.8)*	4.4 (3.7-4.8)*
	week 24	3.4 (2.7-4.4)*	3.5 (2.4-4.3)*	3.4 (2.8-4.5)*
	week 48	3.3 (2.5-4.4)*	3.2 (2.4-4.2)*	3.4 (2.7-4.4)*
SDAI	baseline	30.5 (21.4-42.9)	28.6 (18.1-36.6)	33.1 (22.6-45.9)
	week 12	14.5 (7.1-23.3)*	13.1 (5.1-19.1)*	16.3 (9.3-25.6)*
	week 24	10.5 (5.1-19.0)*	11.0 (5.5-17.6)*	9.1 (4.7-20.4)*
	week 48	10.3 (4.9-17.7)*	10.2 (3.4-15.8)*	10.9 (6.2-18.1)*
CDAI	baseline	28.2 (20.0-37.1)	25.7 (17.0-33.7)	30.0 (21.5-40.5)
	week 12	14.9 (8.0-22.5)*	13.0 (6.8-18.7)*	16.6 (9.0-24.0)*
	week 24	10.0 (5.0-18.0)*	11.0 (4.7-16.0)*	9.3 (5.0-18.0)*
	week 48	10.1 (5.8-17.0)*	10.4 (4.0-16.0)*	10.0 (6.0-17.0)*
CRP, mg/l	baseline	15.6 (6.5-38.0)	15.6 (6.0-38.1)	15.4 (6.9-36.7)
	week 12	5.5 (1.7-12.1)*	6.4 (2.7-10.4)*	5.2 (1.3-12.8)*
	week 24	4.5 (1.0-10.0)*	5.0 (0.8-9.8)*	4.2 (1.0-10.0)*
	week 48	4.0 (0.7-9.0)*	2.9 (0.6-9.6)*	4.0 (0.8-8.9)*
ESR, mm/h	baseline	32.0 (23.0-48.0)	29.0 (16.0-37.0)	32.0 (23.0-49.0)\$
	week 12	21.0 (17.0-33.0)*	20.0 (12.0-33.0)	21.0 (17.0-33.0)*
	week 24	21.0 (12.0-31.0)*	13.0 (9.0-28.0)	21.0 (12.0-31.0)*
	week 48	16.0 (10.0-27.0)*	16.0 (7.0-30.0)*	16.0 (10.0-27.0)*

*p<0.05 from baseline; \$p<0.05 between the groups 1 and 2

Patients of the second group had a higher disease activity and ESR before therapy. The use of TOFA was accompanied by a decrease in the disease activity and the level of acute phase reactants (CRP and ESR) in both groups of patients. By week 48 of treatment, no significant difference between the groups according to the disease activity was detected.

In the first and the second group of pts on the 48-th week of therapy remission/low disease activity was achieved on DAS 28 in 51% and 43% (p=0.57), high disease activity on DAS 28 in 12% and 8% (p=0.48).

Conclusion: An analysis of the data from the Russian national register of patients with RA demonstrated similar efficacy of TOFA among patients who received and did not receive previous biological therapy.

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AB0329 PHYSICIANS' PRE-LAUNCH AWARENESS AND CONCERNS WITH PIPELINE JANUS KINASE INHIBITORS (JAKIS) VERSUS TOFACITINIB AND BARICITINIB IN RHEUMATOID ARTHRITIS IN THE UNITED STATES AND EUROPE

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Background: Clinical data regarding use of tofacitinib and baricitinib in rheumatoid arthritis patients have recently posed safety concerns, with regulatory bodies suggesting limiting use of higher dosages. Investigating physicians' awareness and views of each of these products leading up to their launch, as well as the physicians' patient characteristics, may provide evidence of how pipeline JAKis could be received in the treatment landscape once approved.

Objectives: The objective of the study was to investigate awareness and anticipated concerns of upcoming versus already launched JAKis among a sample of treating rheumatologists in the US and EU5 countries, and assess potential correlation between sampled physicians' views on JAKis and their managed patient characteristics.

Methods: A multi-country, multi-center online medical chart review study of patients with RA was conducted across 2011 – 2019 among rheumatologists in hospitals and private practices to collect de-identified data on a sample of patients who were recently treated with a biologic/JAKi in the USA & EU5 (UK, France, Italy, Spain, Germany). Physicians were screened for duration of practice (3-30 years) and patient volume (≥2 RA biologic/JAKi patients per week) and recruited from a large, geographically representative access panel. Patient charts were recorded for the next 5 eligible patients seen during the screening period. Respondents abstracted patient demographics and personal awareness and concerns for drugs in development. Sites waived local ethics review owing to collection of retrospective de-identified data. Data were analyzed using descriptive statistics.

Results: In Q1 19, 56.2% and 56.2% of sampled US physicians were aware of upadacitinib (upa) and filgotinib (filgo), respectively¹. Prior to US launch,

tofacitinib (tofa) and baricitinib (bari) achieved respective awarenesses of 89.9% (Q4 11, n = 109)² and 85.2% (Q2 17, n = 101)³. Among 262 sampled EU5 rheumatologists, pre-launch awareness in of upa and filgo in Q1 19 was 46.2% and 45.8%¹, while for tofa and bari it was 46.2% and 45.8%, respectively (Q2 16, n = 380)⁴. 'Poor safety profile' was cited as a common anticipated concern for upa and filgo, 9.9% of sampled physicians aware of upa (n=121) and 7.5% of those aware of filgo (n=120)¹, with the respective scores for tofa and bari prior to their launch being 16.9% (n = 296) and 14.5% (n = 227)⁴. Sampled patient characteristics in each physician segment (upa concerned n = 449 patients / non-concerned, n = 155 patients; filgo concerned, n = 454 patients / non-concerned, n = 145 patients) included: (a) age in years 54.6/51, p<0.01; 53.9/51.2, p<0.05 (b) retired employment status 31%/20.6%, p<0.05; 29.5%/20%, p<0.05

Conclusion: In this sample, upa and filgo achieved lower awareness scores, compared to tofa and bari prior their launch. Sampled EU5 physicians were less concerned with upa and filgo's safety profiles, than for the other two JAKis before launch. Sampled physicians holding concerns with upa/filgo manage significantly older patients and a significantly higher number of retired patients. Further investigation using comparator cohort is warranted.

References:

- [1] Ipsos Global Rheumatoid Arthritis Therapy Monitor (Q1 2019, 262 sampled rheumatologists in the EU and 115 sampled rheumatologists in the US reporting on a sample of RA patients seen in their practice; data collected online).
- [2] Ipsos Global Rheumatoid Arthritis Therapy Monitor (Q4 2011, 109 sampled rheumatologists in the US reporting on a sample of RA patients seen in their practice; data collected online).
- [3] Ipsos Global Rheumatoid Arthritis Therapy Monitor (Q2 2017, 101 sampled rheumatologists in the US reporting on a sample of RA patients seen in their practice; data collected online).
- [4] Ipsos Global Rheumatoid Arthritis Therapy Monitor (Q2 2016, 380 sampled rheumatologists in the EU reporting on a sample of RA patients seen in their practice; data collected online).

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AB0330 HIGH REMISSION RATES IN RA – REAL LIFE DATA FROM BARICITINIB

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Background: Recent developments of targeted treatments such as targeted synthetic DMARDs (tsDMARDs) increase the chances of a sustained low disease activity (LDA) or remission state for patients suffering rheumatoid arthritis (RA). tsDMARDs such as baricitinib, an oral inhibitor of the Janus Kinases (JAK1/JAK2) was recently approved for the treatment of RA with an inadequate response to conventional (cDMARD) and biological (bDMARD) therapy. (1, 2).

Objectives: Aim of this study is to analyze the effect of baricitinib on disease activity (DAS28, LDA) in patients with RA in real life, to analyze drug persistence and associate these effects with various baseline characteristics.

Methods: All RA patients were seen in our outpatient clinic. If a patient was switched to a baricitinib due to medical reasons, these patients were included in our prospective, observational study which started in April 2017. Clinical scores (SJC/TJC 76/78), composite scores (DAS28), PROs (HAQ-DI; RAID; FACIT), safety parameters (not reported in this abstract) as well as laboratory biomarkers were collected at each visit every three months. Linear mixed effects models for repeated measurements were used to analyze the time course of disease activity, patient reported outcomes and laboratory results. We estimated the probabilities of continued baricitinib treatment and the probabilities of LDA and remission by DAS-28 as well as Boolean remission up to one year using survival analysis and explored their association with disease characteristics using multivariable Cox regression. All patients gave informed consent. The study is approved by the local ethics.

Results: 95 patients were included and 85 analyzed with available follow-up data until November 2019. Demographics are shown in table 1. Mean follow-up duration after starting baricitinib was 49.3 (28.9) weeks. 51 patients (60%) were on monotherapy. Baricitinib survival (95%CI) was 82% (73% to 91%) at one year. Cumulative number (%probability, 95%CI) of patients that