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アッヴィについて

アッヴィのミッションは現在の深刻な健康課題を解決する革新的な医薬品の創製と提供、そして未 来に向けて医療上の困難な課題に挑むことです。患者さん一人ひとりの人生を豊かなものにする ため次の主要領域に取り組んでいます。免疫疾患、がん、神経疾患、アイケア、ウイルス、ウイメン ズヘルス、消化器疾患、さらにアラガンエステティクスポートフォリオの製品・サービスです。アッヴィ の詳細については、www.abbvie.com をご覧ください。Twitter アカウント@abbvie、Facebook、 LinkedIn や Instagram でも情報を公開しています。

Forward-Looking Statements

Some statements in this news release are, or may be considered, forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995. The words "believe," "expect," "anticipate," "project" and similar expressions, among others, generally identify forward-looking statements. AbbVie cautions that these forward-looking statements are subject to risks and uncertainties, including the impact of the COVID-19 pandemic on AbbVie's operations, results and financial results, that may cause actual results to differ materially from those indicated in the forward-looking statements. Such risks and uncertainties include, but are not limited to, failure to realize the expected benefits of the Allergan acquisition, failure to promptly and effectively integrate Allergan's businesses, significant transaction costs and/or unknown or inestimable liabilities, potential litigation associated with the Allergan acquisition, challenges to intellectual property, competition from other products, difficulties inherent in the research and development process, adverse litigation or government action, and changes to laws and regulations applicable to our industry. Additional information about the economic, competitive, governmental, technological and other factors that may affect AbbVie's operations is set forth in Item 1A, "Risk Factors," of AbbVie's 2019 Annual Report on Form 10-K, which has been filed with the Securities and Exchange Commission (SEC). AbbVie undertakes no obligation to release publicly any revisions to forward-looking statements as a result of subsequent events or developments, except as required by law.

* Key domains include: Patient's global assessment of disease activity; Pain; Function; Inflammation

Superiority for RINVOQ 15 mg to adalimumab could not be demonstrated

† In patients with \ge 3% BSA psoriasis at baseline

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- EMA. RINVOQ Summary of Product Characteristics. Available at: RINVOQ [Summary of Product Characteristics]. AbbVie Deutschland GmbH & Co KG. Available at: www.ema.europa.eu Accessed January 2021.
- 2. RINVOQ [Summary of Product Characteristics]. AbbVie Deutschland GmbH & Co. KG; December 2020. Available at: <u>https://www.ema.europa.eu/en/documents/product-information/rinvoq-epar-product</u>
- 3. Cohen S., et al. Safety Profile of Upadacitinib Up to 3 Years of Exposure in Patients With Rheumatoid Arthritis. ACR Convergence 2020; THU0167.
- McInnes I, et al. Efficacy and Safety of Upadacitinib Versus Placebo and Adalimumab in Patients With Active Psoriatic Arthritis and Inadequate Response to Non-Biologic Disease-Modifying Anti-Rheumatic Drugs (SELECT-PsA-1): a Double-Blind, Randomized Controlled Phase 3 Trial. 2020 EULAR E-Congress; LB0001.
- 5. Mease PJ, Lertratanakul A, Anderson JK, et al. Upadacitinib for psoriatic arthritis refractory to biologics: SELECT-PsA 2. Annals of the Rheumatic Diseases. 2020.
- Van der Heijde D, et al. Efficacy and safety of upadacitinib in patients with active ankylosing spondylitis (SELECT-AXIS 1): a multicentre, randomised, double-blind, placebo-controlled, phase 2/3 trial. The Lancet 2019; 394: 2108-2117.
- 7. Burmester G, et al. Safety Profile of Upadacitinib In Psoriatic Arthritis: Integrated Analysis From Two Phase 3 Trials. ACR Convergence 2020; 1350.
- 8. Cohen S., et al. Safety Profile of Upadacitinib Up to 3 Years of Exposure in Patients With Rheumatoid Arthritis. ACR Convergence 2020; 0237.
- Creaky Joints. What is Ankylosing Spondylitis? Available at: <u>https://creakyjoints.org/education/ankylosing-spondylitis/#:~:text=Ankylosing%20spondylitis%20(AS)%2C%20also,tailbone%2C%20called%20the%20sacroiliac%20joints</u>. Accessed on December 16, 2020
- Diseases & Conditions: Psoriatic Arthritis. 2019. American College of Rheumatology. Available at: <u>https://www.rheumatology.org/I-Am-A/Patient-Caregiver/Diseases-Conditions/Psoriatic-Arthritis</u>. Accessed on: September 10, 2020.
- Schett G, et al. Structural damage in rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis: traditional views, novel insights gained from TNF blockade, and concepts for the future. Arthritis Res & Ther.2011; 13(Suppl1) :s4(1-9)
- 12. Brown, M. and Bradbury, L. New approaches in ankylosing spondylitis. Med J Aust 2017; 206 (5): 192-194. doi: 10.5694/mja16.01111
- 13. Mahmood, F., et al. Current concepts and unmet needs in psoriatic arthritis. Clin Rheumatol. 2018 Feb;37(2):297-305. doi: 10.1007/s10067-017-3908-y. Epub 2017 Nov 13.
- 14. Duarte GV, et al. Psoriatic arthritis. Best Pract Res Clin Rheumatol. 2012 Feb;26(1):147-56. doi: 10.1016/j.berh.2012.01.003.
- 15. Mayo Clinic. Ankylosing Spondylitis. 2019. Available at: <u>http://www.mayoclinic.org/diseases-</u> conditions/ankylosing-spondylitis/symptoms-causes/syc-20354808. Accessed: December 2020.
- 16. A Study Comparing Upadacitinib (ABT-494) to Placebo and to Adalimumab in Participants With Psoriatic Arthritis Who Have an Inadequate Response to at Least One Non-Biologic Disease Modifying Anti-Rheumatic Drug (SELECT PsA 1). ClinicalTrials.gov. 2020. Available at: https://clinicaltrials.gov/ct2/show/NCT03104400. Accessed: December 2020
- A Study Comparing Upadacitinib (ABT-494) to Placebo in Participants With Active Psoriatic Arthritis Who Have a History of Inadequate Response to at Least One Biologic Disease Modifying Anti-Rheumatic Drug (SELECT-PsA 2). Clinicaltrials.gov. 2020. Available at: <u>https://clinicaltrials.gov/ct2/show/NCT03104374</u>. Accessed: December 2020
- A Study Evaluating the Safety and Efficacy of Upadacitinib in Subjects With Active Ankylosing Spondylitis (SELECT Axis 1). ClinicalTrials.gov. 2020. Available at: <u>https://clinicaltrials.gov/ct2/show/study/NCT03178487</u>. Accessed: December 2020.
- Pipeline Our Science | AbbVie. AbbVie. 2019. Available at: <u>https://www.abbvie.com/our-science/pipeline.html</u>. Accessed: December 2020.
- Burmester GR, et al. Safety and efficacy of upadacitinib in patients with rheumatoid arthritis and inadequate response to conventional synthetic disease-modifying anti-rheumatic drugs (SELECT-NEXT): a randomised, double-blind, placebo-controlled phase 3 trial. Lancet. 2018 Jun 23;391(10139):2503-2512. doi: 10.1016/S0140-6736(18)31115-2. Epub 2018 Jun 13.
- 21. A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of ABT-494 for the Induction of Symptomatic and Endoscopic Remission in Subjects With Moderately to Severely Active Crohn's Disease

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Who Have Inadequately Responded to or Are Intolerant to Immunomodulators or Anti-TNF Therapy. ClinicalTrials.gov. 2020. Available at: <u>https://clinicaltrials.gov/ct2/show/NCT02365649</u>. Accessed: December 2020.

- 22. A Study to Evaluate the Safety and Efficacy of ABT-494 for Induction and Maintenance Therapy in Subjects With Moderately to Severely Active Ulcerative Colitis. ClinicalTrials.gov. 2020. Available at: https://clinicaltrials.gov/ct2/show/NCT02819635. Accessed: December 2020.
- 23. A Study to Compare Safety and Efficacy of Upadacitinib to Dupilumab in Adult Participants With Moderate to Severe Atopic Dermatitis (Heads Up). ClinicalTrials.gov. 2020. Available at: https://clinicaltrials.gov/ct2/show/NCT03738397. Accessed: December 2020.
- A Study to Evaluate Efficacy and Safety of Upadacitinib in Adult Participants With Axial Spondyloarthritis (SELECT AXIS 2). ClinicalTrials.gov. 2020. Available at: <u>https://clinicaltrials.gov/ct2/show/NCT04169373</u>. Accessed: December 2020.
- A Study to Evaluate the Safety and Efficacy of Upadacitinib in Participants With Giant Cell Arteritis (SELECT-GCA). ClinicalTrials.gov. 2020. Available at: <u>https://clinicaltrials.gov/ct2/show/NCT03725202</u>. Accessed: December 2020.
- A Study to Evaluate the Efficacy and Safety of Upadacitinib in Subjects With Takayasu Arteritis (SELECT-TAK). ClinicalTrials.gov. 2020. Available at: <u>https://clinicaltrials.gov/ct2/show/record/NCT04161898</u>. Accessed: December 2020.