Pfizer Logo

Roivant and Pfizer Unveil Priovant Therapeutics and Ongoing Registrational Studies for Oral Brepocitinib in Dermatomyositis and Lupus

Tuesday, June 28, 2022 - 06:00am

- *Brepocitinib is a potential first-in-class dual, selective inhibitor of TYK2 and JAK1; in all five placebo-controlled studies completed to date, oral brepocitinib generated statistically significant and clinically meaningful results*
- *Priovant is developing brepocitinib in severe autoimmune diseases with few approved therapies and where dual inhibition of TYK2 and JAK1 may provide greater efficacy than inhibiting either alone*
- *A single registrational Phase 3 trial evaluating oral brepocitinib in dermatomyositis (VALOR) was initiated earlier this quarter*
- *An ongoing Phase 2b study in systemic lupus erythematosus (SLE) , designed to serve as one of two registrational studies, is expected to generate top-line results in 2H 2023*

NEW YORK--(BUSINESS WIRE)-- Roivant Sciences and Pfizer today announced the unveiling of Priovant Therapeutics, dedicated to developing and commercializing novel therapies for autoimmune diseases with the greatest morbidity and mortality. Priovant was established in September 2021 through a transaction between Roivant (Nasdaq: ROIV) and Pfizer (NYSE: PFE), in which Pfizer licensed oral and topical brepocitinib's global development rights and US and Japan commercial rights to Priovant. Pfizer holds a 25% equity ownership interest in Priovant.

This press release features multimedia. View the full release here:
https://www.businesswire.com/news/home/20220628005336/en/

Brepocitinib is a potential first-in-class dual inhibitor of TYK2 and JAK1, a novel mechanism of action expected to potentially provide greater efficacy in multiple highly inflammatory autoimmune diseases, as compared to agents that inhibit either TYK2 or JAK1 alone. Priovant is developing oral brepocitinib as a franchise across multiple orphan and specialty autoimmune diseases with few approved therapies, high morbidity and mortality, and pathobiologies for which both TYK2 and JAK1 inhibition are expected to contribute to efficacy. Oral brepocitinib is being evaluated in two ongoing registrational programs. Priovant recently initiated a single registrational Phase 3 study in dermatomyositis (VALOR). A large, global Phase 2b study in SLE, designed to serve as one of two registrational studies, is close to fully enrolled with data anticipated in 2H 2023.

"Roivant has a proven track record in late-stage inflammation and immunology drug development, which is why we are confident that Priovant will successfully continue the development of much needed innovative treatments for these patients," said Mikael Dolsten, Chief Scientific Officer, President, Worldwide Research, Development and Medical at Pfizer. "This collaboration will enable allocation of resources to advance development of brepocitinib while allowing Pfizer to focus on diversifying its pipeline so that patients may benefit from potential

options against inflammatory diseases."

Oral brepocitinib has been evaluated in 14 completed Phase 1 and Phase 2 studies, including five placebo-controlled Phase 2 studies in psoriatic arthritis, plaque psoriasis, ulcerative colitis, alopecia areata, and hidradenitis suppurativa. All five of these placebo-controlled Phase 2 studies generated statistically significant and clinically meaningful results. Oral brepocitinib's safety database includes over 1,000 exposed subjects and suggests a safety profile similar to those of approved JAK inhibitors.

Priovant recently initiated a single registrational Phase 3 study evaluating oral brepocitinib in dermatomyositis (VALOR). Dermatomyositis is an immune-mediated disease of the skin and muscles. Patients with dermatomyositis usually present with a characteristic skin rash and debilitating muscle weakness, which may lead to significant functional impairment and/or disfigurement. Substantially increased risk of interstitial lung disease, malignancy, and heart failure contribute to an estimated five-year mortality rate of 10-40%.[i] There is a substantial unmet need for novel, efficacious and convenient therapies that address the underlying pathophysiology of dermatomyositis.

"There is an urgent need for novel, targeted therapies for dermatomyositis, a devastating disease with few safe and effective treatments," said Ruth Ann Vleugels, MD, MPH, Director of the Connective Tissue Disease Clinics and Autoimmune Skin Diseases Program at Brigham and Women's Hospital/Harvard Medical School. "Brepocitinib is a particularly promising agent, as its dual inhibition of TYK2 and JAK1 may result in superior blockade of type I interferon, a key cytokine family implicated in dermatomyositis pathogenesis."

Oral brepocitinib is being evaluated in a large, global Phase 2b study in SLE, designed to serve as one of two registrational studies. Lupus is a clinically heterogeneous autoimmune disease that can impact nearly all major organ systems. While there are two approved targeted biologics for lupus, many patients respond inadequately. Like dermatomyositis, lupus pathobiology is characterized by dysregulations in type I interferon and other TYK2- and JAK1-mediated proinflammatory cytokines.

In addition to brepocitinib, Pfizer has also licensed ropsacitinib, a selective TYK2 inhibitor, to Priovant.

About Priovant Therapeutics

Priovant is a clinical-stage biotechnology company focused on delivering novel therapies for autoimmune diseases with the greatest morbidity and mortality. Priovant is developing oral brepocitinib, a potential first-in-class dual inhibitor of TYK2 and JAK1, as a franchise across multiple severe autoimmune diseases. Oral brepocitinib is currently being evaluated in potentially registrational studies in two indications. VALOR, a single Phase 3 study evaluating brepocitinib in dermatomyositis, is currently enrolling subjects. A large Phase 2b study in systemic lupus erythematosus, designed to serve as one of two registrational studies, is expected to generate top-line results in 2H 2023. Priovant also holds global development and commercial rights to topical brepocitinib in the US and Japan and to ropsacitinib, a selective TYK2 inhibitor, in the US. For more information, please visit www.priovanttx.com.

About Roivant Sciences

Roivant's mission is to improve the delivery of healthcare to patients by treating every inefficiency as an opportunity. Roivant develops transformative medicines faster by building technologies and developing talent in creative ways, leveraging the Roivant platform to launch 'Vants' – nimble and focused biopharmaceutical and health technology companies. For more information, please visit www.roivant.com.

About Pfizer: Breakthroughs That Change Patients' Lives

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

Roivant Sciences Forward-Looking Statements

This press release contains forward-looking statements. Statements in this press release may include statements that are not historical facts and are considered forward-looking within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which are usually identified by the use of words such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intends," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "would" and variations of such words or similar expressions. The words may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. We intend these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Exchange Act.

Our forward-looking statements include, but are not limited to, statements regarding our or our management team's expectations, hopes, beliefs, intentions or strategies regarding the future, and statements that are not historical facts, including statements about the clinical and therapeutic potential of our product candidates, the availability and success of topline results from our ongoing clinical trials and any commercial potential of our product candidates. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements.

Although we believe that our plans, intentions, expectations and strategies as reflected in or suggested by those forward-looking statements are reasonable, we can give no assurance that the plans, intentions, expectations or strategies will be attained or achieved. Furthermore, actual results may differ materially from those described in the forward-looking statements and will be affected by a number of risks, uncertainties and assumptions, including, but not limited to, those risks set forth in the Risk Factors section of our filings with the U.S. Securities and Exchange Commission. Moreover, we operate in a very competitive and rapidly changing environment in which new risks emerge from time to time.

These forward-looking statements are based upon the current expectations and beliefs of our management as of the date of this press release, and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Except as required by applicable law, we assume no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

Pfizer Disclosure Notice

The information contained in this release is as of June 28, 2022. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about, among other things, brepocitinib, ropsacitinib, a transaction between Pfizer and Roivant and Priovant Therapeutics, including their potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from the clinical studies; whether and when any applications may be filed for any potential indications for brepocitinib, ropsacitinib or any of Pfizer's product candidates in any jurisdictions; whether and when regulatory authorities may approve any such applications that may be filed for brepocitinib, ropsacitinib or any of Pfizer's product candidates, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether brepocitinib, ropsacitinib or any of Pfizer's product candidates will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of brepocitinib, ropsacitinib or any of Pfizer's product candidates; whether the transaction with Roivant will be successful; uncertainties regarding the impact of COVID-19 on Pfizer's business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

---

[i] Liu et al, *Oncol Letters* (2018)

Category: Investments

View source version on businesswire.com: https://www.businesswire.com/news/home/20220628005336/en/

Roivant
Paul Davis
Paul.davis@roivant.com

Pfizer
PfizerMediaRelations@Pfizer.com
+1 (212) 733-1226

Priovant
Daniel Herz-Roiphe
daniel.herz-roiphe@priovanttx.com

Source: Pfizer Inc.