
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

FORM 8-K

**Current Report Pursuant
to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

Date of Report (Date of earliest event Reported): April 9, 2020

THERAVANCE BIOPHARMA, INC.

(Exact Name of Registrant as Specified in its Charter)

Cayman Islands
(State or Other Jurisdiction of
Incorporation)

001-36033
(Commission File Number)

98-1226628
(I.R.S. Employer Identification Number)

**PO Box 309
Ugland House, South Church Street
George Town, Grand Cayman, Cayman Islands KY1-1104
(650) 808-6000**

(Addresses, including zip code, and telephone number, including area code, of principal executive offices)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:
Ordinary Share \$0.00001 Par Value

Trading Symbol(s)
TBPH

Name of each exchange on which registered:
NASDAQ Global Market

Item 8.01 Other Events.

On April 9, 2020, Theravance Biopharma, Inc. (the “Company”) issued a press release and will hold a conference call to discuss the press release. A copy of the Company’s press release is attached hereto as Exhibit 99.1 to this Current Report and a copy of materials that will be presented on the call is attached hereto as Exhibit 99.2 to this Current Report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

[99.1](#) [Press Release dated April 9, 2020](#)

[99.2](#) [Slide deck](#)

104 Cover Page Interactive Data File (cover page XBRL tags embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

THERAVANCE BIOPHARMA, INC.

Date: April 9, 2020

By: /s/ Andrew Hindman

Andrew Hindman

Senior Vice President and Chief Financial Officer



Theravance Biopharma Responds to COVID-19 Pandemic by Advancing TD-0903 to Treat Hospitalized Patients with Acute Lung Injury

- § *Clinical Trial Application (CTA) submitted in the United Kingdom for first in human study of TD-0903, an investigational lung-selective nebulized JAKi with potential to treat Acute Lung Injury caused by COVID-19*
- § *Near-term clinical development program enables progression from healthy volunteers to hospitalized COVID-19 patients*

DUBLIN, IRELAND and SOUTH SAN FRANCISCO, CA - APRIL 9, 2020 -- Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma" or the "Company"), a diversified biopharmaceutical company primarily focused on the discovery, development and commercialization of organ-selective medicines, today announced that it is advancing TD-0903, a lung-selective nebulized Janus kinase inhibitor (JAKi) into clinical development to assess its utility in preventing the cytokine storm associated with Acute Lung Injury (ALI) in patients hospitalized due to COVID-19, with the ultimate goal of preventing progression to Acute Respiratory Distress Syndrome (ARDS).

"In response to the unprecedented healthcare challenges presented by the emergence of COVID-19, we have combined our immunology and respiratory medicine expertise to accelerate development of our nebulized lung-selective JAK inhibitor, TD-0903. With great urgency, we have redirected our program to treat the acute lung injury caused by COVID-19," said Rick E Winningham, Chief Executive Officer. "We recognize how critical it is to help those suffering from shortness of breath and low oxygen levels, including those who need intensive care and ventilation, to address the effects of profound lung hyperinflammation. TD-0903 could provide benefit to hospitalized patients by preventing the progression of lung hyperinflammation and reducing the requirement for, or the duration of, assisted ventilation. As a result, this could improve utilization of limited hospital critical care resources."

"We are pleased to be able to direct our resources and expertise towards helping to treat COVID-19," said Brett Haumann, M.D. Chief Medical Officer. "Janus kinase inhibitors have the potential to inhibit a broad set of immune-modulatory pathways that could prove to be effective in dampening the abnormal immune response that occurs in the lungs of some patients. The nebulized formulation of our lung-selective inhaled JAK inhibitor will allow TD-0903 to be administered directly to the lung in a number of hospitalized settings, including patients who can breathe unaided in the ward, as well as in the ICU setting in patients who require non-invasive or mechanical ventilation. If our initial CTA submission for this study in healthy volunteers is approved and the study is successful, we intend to study TD-0903 in COVID-19 patients in the very near future. We are proud of the tremendous efforts of the global team of Theravance Biopharma scientists and physicians that has enabled us to rapidly progress TD-0903, and we are grateful for their collaboration and dedication to continue its advancement."

About TD-0903

TD-0903 is a lung-selective, nebulized pan-JAK inhibitor that was discovered and developed at Theravance Biopharma. TD-0903 has been shown in experimental murine models to have potent, broad inhibition of JAK-STAT signaling in the airways following challenges with multiple cytokines. By its mechanism, TD-0903 has the potential to block release of cytokines and chemokines that may be associated with acute lung injury and the initiation of a cytokine storm syndrome. Preclinical studies suggest that TD-0903 has a very high lung:plasma ratio and rapid metabolic clearance resulting in low systemic exposure, compatible with its lung selectivity. TD-0903 is administered via nebulized inhalation solution, which further enhances its lung selectivity. Preclinical pharmacodynamic studies indicate that TD-0903 has an extended duration of action that should enable once or twice daily dosing in humans.

As disclosed initially at Theravance Biopharma's December 2018 Research and Development Day, the Company indicated the initial clinical application of TD-0903 would be to explore its utility in preventing/delaying graft rejection among individuals receiving lung transplantation. Although this is still a potential clinical application for TD-0903, in response to the current COVID-19 pandemic, the Company has prioritized activities toward assessing the potential for TD-0903 to treat hospitalized COVID-19 patients who become short of breath and whose blood oxygen levels begin to drop. These patients appear to be at increased risk of respiratory complications including Acute Lung Injury (ALI) and Acute Respiratory Distress Syndrome (ARDS). They may also require prolonged hospitalization, continuous oxygen and, in the most severe cases, admission to ICU to assist their breathing with non-invasive and/or mechanical ventilation. Treatment with JAK inhibition is recognized as an important anti-inflammatory mechanism to potentially reduce the hyperinflammation seen in hospitalized COVID-19 patients who develop ALI and ARDS.¹

Upon review and approval of the initial CTA, the Company is planning to initiate a Phase 1 study this month in the United Kingdom (UK), starting with single- and multiple-ascending doses in healthy volunteers to assess safety. Upon regulatory review and approval, the program will then move to a nested Phase 2 study in hospitalized patients with COVID-19. The Phase 2 study will consist of two parts. The first part will assess the safety, tolerability and clinical response to treatment in sequential ascending dose cohorts of COVID-19 patients in the UK. This part of the study will not be formally powered for efficacy but will inform the selection of dose(s) for the second part. The second part of the Phase 2 study will be a larger, multi-center study conducted at hospital-based clinical sites in the UK, and potentially other clinical sites in the European Union and United States. Both of the latter territories would join the Phase 2 study program following review and approval of the relevant regulatory filings required by the European Medicines Authority (EMA) and Food and Drug Administration (FDA). Further details on the program, including more on Phase 1 and Phase 2 studies will be provided once these studies have been approved by the appropriate regulatory and ethics review authorities.

Theravance Biopharma's efforts leverage years of experience in developing lung-selective medicines to treat respiratory disease.

¹ The Lancet, March 13, 2020, "COVID-19: consider cytokine storm syndromes and immunosuppression" Mehta, McAuley, Brown, Sanchez, Tattersall, Manson, et al.



About the Inhaled JAK Inhibitor Program

JAK inhibitors function by inhibiting the activity of one or more of the Janus kinase family of enzymes (JAK1, JAK2, JAK3, TYK2) that play a key role in cytokine signaling. Inhibiting these JAK enzymes interferes with the JAK/STAT signaling pathway and, in turn, modulates the activity of a wide range of pro-inflammatory cytokines. Limiting JAK inhibition to the lung is expected to improve therapeutic index relative to systemic inhibition. Thus, inhaled JAK inhibitors with lung-restricted exposure are of high interest as potential treatments for respiratory illness.

TD-8236 is the Company's most advanced investigational pan-Janus kinase (JAK) inhibitor currently designed for delivery to the lungs using a dry powder inhaler (DPI). Similar to TD-0903, TD-8236 is a lung-selective agent designed to inhibit the JAK family of enzymes in lung tissue with limited systemic exposure. An extensive set of preclinical pharmacological studies and toxicological studies support its current clinical development in the primary indication of moderate to severe asthma. Insights from the ongoing clinical development of TD-8236 DPI are informing the Company's confidence to bring TD-0903 forward for the treatment of COVID-19 acute lung injury.

In addition, Theravance Biopharma is currently assessing the impact of the COVID-19 pandemic on its operations, including on the commercial operations associated with YUPELRI® (revefenacin inhalation solution) and on the conduct of its clinical development programs for TD-1473, ampreloxetine and TD-8236. The situation continues to evolve as the pandemic's effects are felt around the world. The Company has implemented a comprehensive business continuity plan to support its performance, and it remains well capitalized to advance the company despite the obstacles presented by the current environment. The Company will provide further program updates during its Q1 financial results and business update call in early May 2020.

Conference Call and Live Webcast Today at 8:00 a.m. ET

Theravance Biopharma will hold a conference call and live webcast accompanied by slides today at 8:00 a.m. ET (5:00 a.m. PT / 1:00 p.m. GMT). To participate in the live call by telephone, please dial (855) 296-9648 from the U.S., or (920) 663-6266 for international callers and use the confirmation code 5076939. Those interested in listening to the conference call live via the internet may do so by visiting Theravance Biopharma's website at www.theravance.com, under the Investor Relations section, Presentations and Events.

A replay of the conference call will be available on Theravance Biopharma's website for 30 days through May 9, 2020. An audio replay will also be available through 11:00 a.m. ET on April 16, 2020 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and then entering confirmation code 5076939.

About Theravance Biopharma

Theravance Biopharma, Inc. ("Theravance Biopharma") is a diversified biopharmaceutical company primarily focused on the discovery, development and commercialization of organ-selective medicines.



Our purpose is to create transformational medicines to improve the lives of patients suffering from serious illnesses. Our research is focused in the areas of inflammation and immunology.

In pursuit of our purpose, we apply insights and innovation at each stage of our business and utilize our internal capabilities and those of partners around the world. We apply organ-selective expertise to biologically compelling targets to discover and develop medicines designed to treat underserved localized diseases and to limit systemic exposure, in order to maximize patient benefit and minimize risk.

These efforts leverage years of experience in developing lung-selective medicines to treat respiratory disease, including FDA-approved YUPELRI® (revefenacin) inhalation solution indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD). Our pipeline of internally discovered programs is targeted to address significant patient needs.

We have an economic interest in potential future payments from Glaxo Group Limited or one of its affiliates (GSK) pursuant to its agreements with Innoviva, Inc. relating to certain programs, including TRELEGY ELLIPTA. For more information, please visit www.theravance.com.

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This press release and the conference call will contain certain "forward-looking" statements as that term is defined in the Private Securities Litigation Reform Act of 1995 regarding, among other things, statements relating to goals, plans, objectives, expectations and future events. Theravance Biopharma intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. Examples of such statements include statements relating to the Company's strategies, plans and objectives, the Company's regulatory strategies and timing of clinical studies (including the data therefrom), the potential benefits and mechanisms of action of the Company's product and product candidates, particularly TD-0903, the Company's expectations for product candidates through development and potential regulatory approval and commercialization (including their potential as components of combination therapies), expectations for the repayment of its notes and the expected future commercial performance of TRELEGY ELLIPTA. These statements are based on the current estimates and assumptions of the management of Theravance Biopharma as of the date of the press release and the conference call and are subject to risks, uncertainties, changes in circumstances, assumptions and other factors that may cause the actual results of Theravance Biopharma to be materially different from those reflected in the forward-looking statements. Important factors that could cause actual results to differ materially from those indicated by such forward-looking statements include, among others, risks related to: impacts of the COVID-19 global pandemic on our business, delays or difficulties in commencing, enrolling or completing clinical studies, the potential that results from clinical or non-clinical studies indicate the Company's compounds or product candidates are unsafe or ineffective, risks that product candidates do not obtain approval from regulatory authorities, the feasibility of undertaking future clinical trials for our product candidates based on policies and feedback from regulatory authorities, dependence on third parties to conduct clinical studies, delays or failure to achieve and maintain regulatory approvals for product candidates, risks of collaborating with or relying on third parties to discover, develop, manufacture and commercialize products, risks associated with establishing and maintaining sales, marketing and distribution capabilities with appropriate technical expertise and supporting infrastructure, potential future disagreements with Innoviva, Inc. and TRC LLC, the uncertainty of arbitration and litigation and the possibility that an arbitration award or litigation result could be adverse to the Company. Other risks affecting Theravance Biopharma are described under the heading "Risk Factors" and elsewhere in Theravance Biopharma's Form 10-K filed with the Securities and Exchange Commission (SEC) on February 27, 2020, in the Form S-3 filed with the SEC on December 3, 2019 and in the Prospectus Supplement filed with the SEC on February 12, 2020. In addition to the risks described above and in Theravance Biopharma's filings with the SEC, other unknown or unpredictable factors also could affect Theravance Biopharma's results. No forward-looking statements can be guaranteed and actual results may differ materially from such statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Theravance Biopharma assumes no obligation to update its forward-looking statements on account of new information, future events or otherwise, except as required by law.



Contact Information

Gail B. Cohen
Corporate Communications and Investor Relations
917-214-6603

TD-0903: Nebulized pan-JAKi for Acute Lung Injury Associated with COVID-19

April 9, 2020



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Forward looking statements

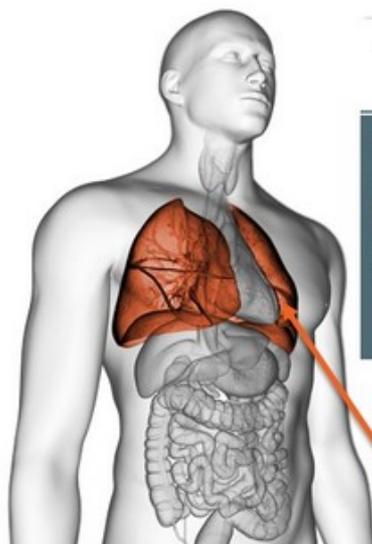
Under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, the company cautions investors that any forward-looking statements or projections made by the company are subject to risks and uncertainties that may cause actual results to differ materially from the forward-looking statements or projections.

Examples of forward-looking statements in this presentation may include the Company's strategies, plans and objectives, the Company's regulatory strategies and timing of clinical studies (including the data therefrom), the potential characteristics, benefits and mechanisms of action of the Company's product and product candidates, the potential that the Company's research programs will progress product candidates into the clinic, the Company's expectations for product candidates through development and potential regulatory approval and commercialization (including their differentiation from other products or potential products), the Company's expectations regarding its allocation of resources, product sales or profit share revenue, the repayment of its notes, expected future commercial performance of Trelegy Ellipta and the Company's expectations for its 2020 operating loss, excluding share-based compensation and other financial results.

The company's forward-looking statements are based on the estimates and assumptions of management as of the date of this presentation and are subject to risks and uncertainties that may cause the actual results to be materially different than those projected, such as risks related to impacts of the COVID-19 global pandemic on our business, delays or difficulties in commencing, enrolling or completing clinical studies, the potential that results from clinical or non-clinical studies indicate the Company's compounds or product candidates are unsafe or ineffective, risks that product candidates do not obtain approval from regulatory authorities, the feasibility of undertaking future clinical trials for our product candidates based on policies and feedback from regulatory authorities, dependence on third parties to conduct clinical studies, delays or failure to achieve and maintain regulatory approvals for product candidates, risks of collaborating with or relying on third parties to discover, develop, manufacture and commercialize products, risks associated with establishing and maintaining sales, marketing and distribution capabilities with appropriate technical expertise and supporting infrastructure, potential future disagreements with Innoviva, Inc. and TRC LLC, the uncertainty of arbitration and litigation and the possibility that an arbitration award or litigation result could be adverse to the Company.

Other risks affecting the company are described under the heading "Risk Factors" and elsewhere in the Company's Form 10-K filed with the SEC on February 27, 2020, and other periodic reports filed with the SEC.

Lung selective JAK inhibitor targeted at cytokine storm



THE LANCET

Log in

CORRESPONDENCE | VOLUME 395, ISSUE 10229, P1033-1034, MARCH 28, 2020

COVID-19: consider cytokine storm syndromes and immunosuppression

Puja Mehta · Daniel F McAuley · Michael Brown · Emille Sanchez · Rachel S Tattersall · Jessica J Manson · et al.

Show all authors Published: March 16, 2020 · DOI: [https://doi.org/10.1016/S0140-6736\(20\)30628-0](https://doi.org/10.1016/S0140-6736(20)30628-0)

PlumX Metrics

As of March 12, 2020, coronavirus disease 2019 (COVID-19) has been confirmed in 125 048 people worldwide, carrying a mortality of approximately 3-7%,¹ compared with a mortality rate of less than 1% from influenza. There is an urgent need for effective treatment. Current focus has been on the development of novel therapeutics, including antivirals and vaccines. Accumulative evidence suggests that a subgroup of patients

TD-0903

Pan-JAK Inhibitor Designed Specifically for Lung Diseases

Leveraging >20 years of experience in design of novel respiratory drugs

Respiratory experience

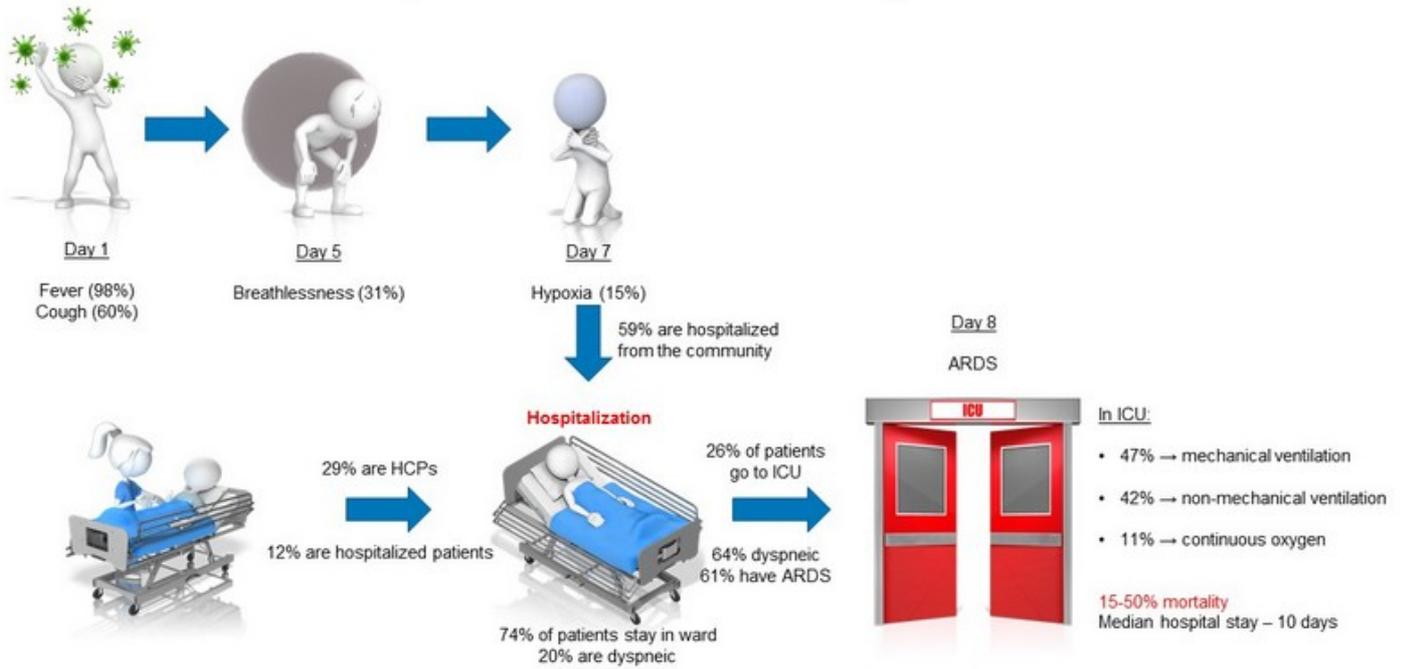
- ▶ Three commercial programs with GSK collaboration* (ANORO ELLIPTA, BREO ELLIPTA, TRELEGY ELLIPTA)
- ▶ Discovered and developed YUPELRI® (revefenacin) inhalation solution, the first and only once-daily, nebulized bronchodilator approved for maintenance treatment for COPD

Organ-selective therapeutic targets

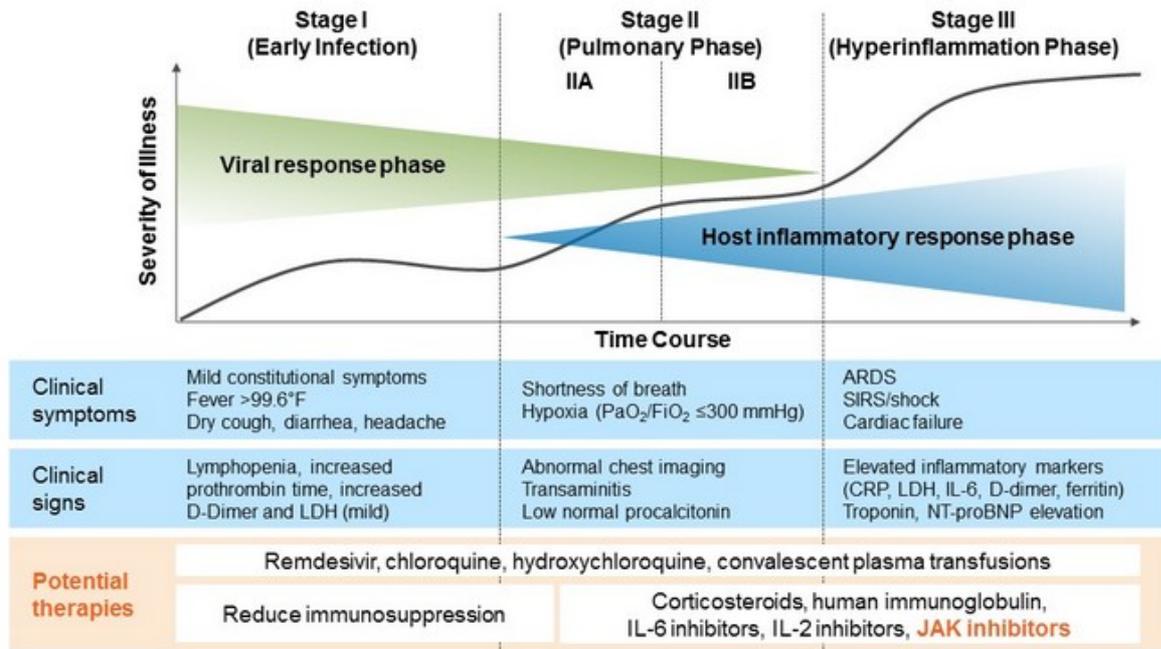
- ▶ Driving discovery, development and commercialization of organ-selective small-molecule medicines



Clinical course for patients who develop ALI and ARDS

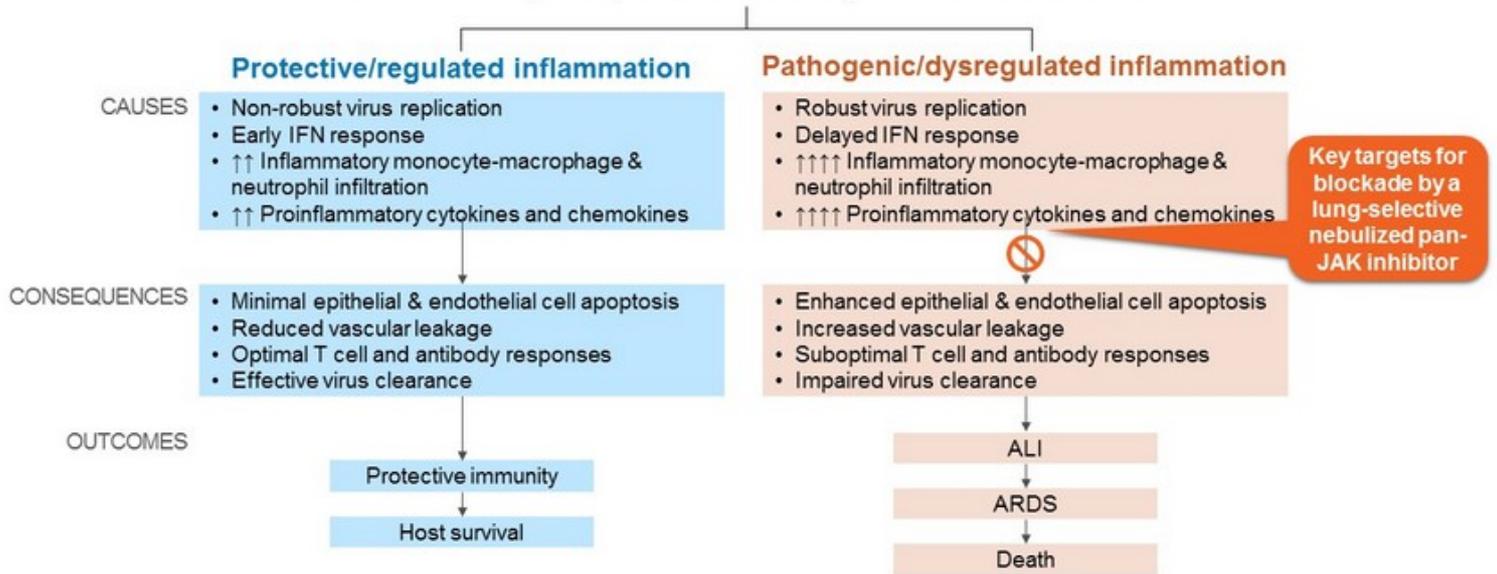


Host Inflammatory Response to COVID-19 Drives ALI and ARDS



Inhaled pan-JAK inhibitor could suppress dysregulated immune response (“cytokine storm”) in the lung

Inflammatory Response to Pathogenic hCoV Infections

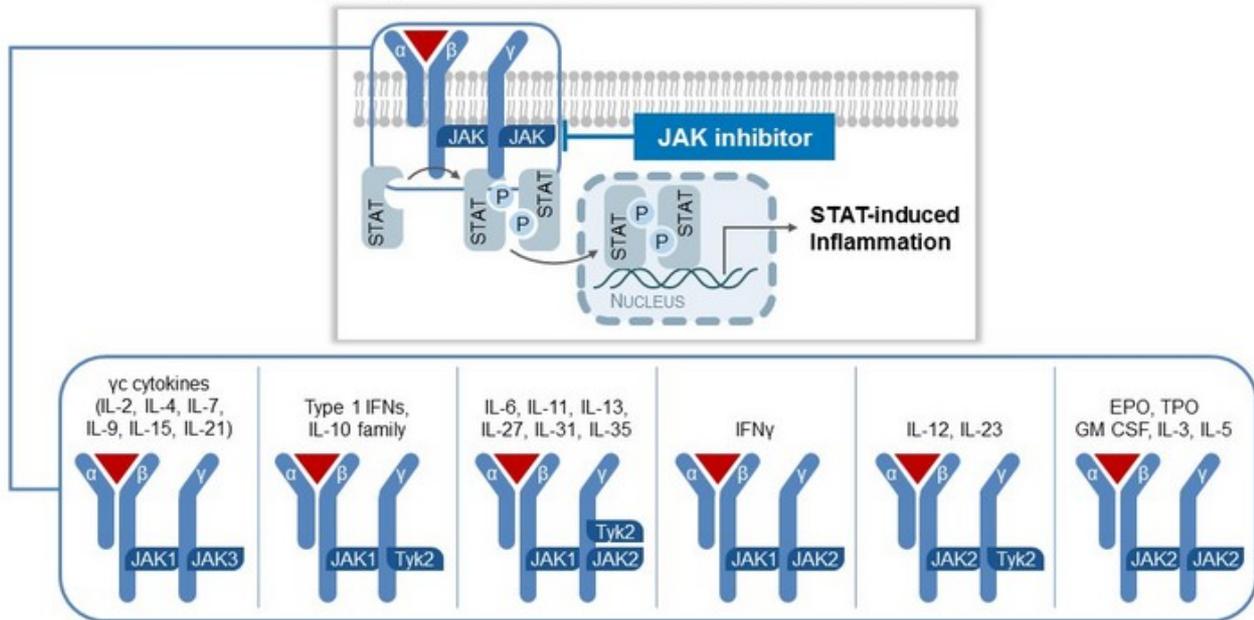


COVID-19: consider cytokine storm syndromes and immunosuppression

Puja Mehta • Daniel F McAuley • Michael Brown • Emilie Sanchez • Rachel S Tattersall • Jessica J Manson ✉ • et al.

- A cytokine profile resembling sHLH is associated with COVID-19 disease severity, characterized by increased IL-2, IL-7, GCSF, IP-10, MCP-1, MIP1- α and TNF- α
- A multicenter, randomized controlled trial of tocilizumab (IL-6 receptor blockade, licensed for cytokine release syndrome), has been approved in patients with COVID-19 pneumonia and elevated IL-6 in China (ChiCTR2000029765)

Pan-JAK inhibition: decrease signaling of multiple pro-inflammatory cytokines associated with COVID-19



TD-0903: Potent, lung-selective inhaled pan-JAKi

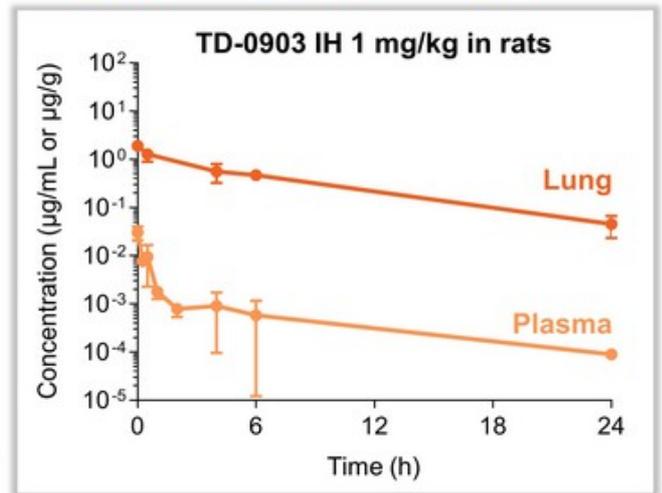
DESIGN: MAXIMAL ANTI-INFLAMMATORY ACTIVITY IN PULMONARY TISSUE WHILE MINIMIZING SYSTEMIC EXPOSURE

- ▶ High affinity for JAK1, JAK2, JAK3, and Tyk2 kinase domains
- ▶ High potency for inhibition of cytokine-induced activation of JAK-STAT signaling pathways
 - In vitro: human epithelial and immune cells
 - In vivo: murine inhalation cytokine-challenge models
- ▶ Lung-selective design
 - High lung to plasma ratios (rat ~170, dog ~850)
 - Rapid systemic clearance with no evidence of systemic immunosuppression
 - PK/PD modeling supports extended duration of action
- ▶ Well tolerated in 28-day rat and dog GLP studies
- ▶ Phase 1 FIH Study - Ethics Committee submission approved
- ▶ CTA enabling package submitted and under review with MHRA

JAK
KINASE
DOMAIN

LUNG
EPITHELIAL

IMMUNE
CELLS



Hospitalized COVID-19 patients with ALI have varying levels of ventilatory support

**Mechanical
Ventilation**



**High-Flow
Nasal Cannulation**



**Non-Invasive
Ventilation**



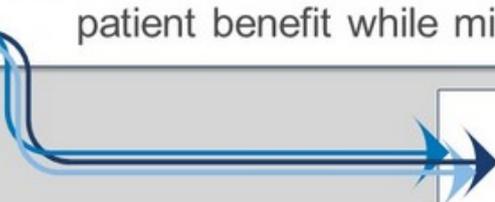
**Mask
Oxygen**



Nebulized delivery of an inhaled JAKi is optimal for hospital use

Our Mission

Transform the treatment of serious diseases through the discovery, development, and commercialization of ***organ-selective medicines*** designed to maximize patient benefit while minimizing patient risk



Apply lung selective JAK inhibition to fight cytokine storm in COVID-19