Onconova Therapeutics, Inc. and Trawsfynydd Therapeutics, Inc. Announce Business Combination to Form Traws Pharma, Inc, a Best-in-Class Virology and Oncology Company

Apr 02, 2024

- *Closing cash balance of approximately $28 million expected from concurrent private placement led by OrbiMed and Torrey Pines*
- *Funding expected to advance development of three potential best-in-class/class leading assets: viroksavir, a cap-dependent endonuclease inhibitor for influenza; travaltrelvir, a protease inhibitor for COVID19; and narazaciclib, a next generation CDK4/6 inhibitor for low grade endometriod endometrial cancer (LGEEC)*
- *Multiple near-term catalysts, for viroksavir and travaltrevir in 2024, with first top-line read-outs expected in H2 2024*
- *Traws Pharma to be led by incoming CEO, Werner Cautreels, Ph.D.*
- *Combined board to be led by Executive Chairman Iain Dukes DPhil (OrbiMed) along with Nikolay Savchuk, Ph.D. (Torrey Pines)*
- *Companies to host joint webcast, April 2, 2024 at 8:30 a.m. ET*

NEWTOWN, Pa. and ROCKVILLE, Md., April 02, 2024 (GLOBE NEWSWIRE) -- Onconova Therapeutics, Inc. (NASDAQ: ONTX) ("Onconova"), and Trawsfynydd Therapeutics, Inc. ("Trawsfynydd"), a privately-held biotechnology company developing next-generation, best-in-class antivirals for influenza, COVID and other infectious diseases, today announced that the companies have entered into a definitive merger agreement to combine in an all-stock transaction (the "Merger"). Under the terms of the agreement, Onconova acquired 100% of Trawsfynydd's outstanding equity interests. In connection with the transaction and concurrent with the Merger, the combined company which has been renamed "Traws Pharma, Inc." ("Traws") will trade on NASDAQ under the new ticker symbol "TRAW", commencing prior to the opening of trading Wednesday, April 3, 2024.

In connection with the Merger, Traws announced that it will raise $14 million in a committed private placement financing by OrbiMed and Torrey Pines, expected to close on April 3, 2024. Upon closing of the private placement, Traws expects to have in excess of $28 million of cash and cash equivalents from the proceeds of the private placement and cash from both companies. These proceeds will be used to advance the Traws' programs through multiple clinical data catalysts and complete the dose ranging study for narazaciclib.

"I am pleased to announce the combination of Onconova and Trawsfynydd at this important time, as Trawsfynydd readies to initiate Phase 2 studies in H2 2024 for its lead antiviral programs for influenza and COVID19, supported by advisors with unparalleled expertise in viral disease, and Onconova is preparing to finalize the recommended Phase 2 dose (RP2D) for narazaciclib," **said Dr. Cautreels incoming Chief Executive Officer of the combined company.**

Commented Steven Fruchtman, M.D., President and Chief Executive Officer of Onconova and President and CSO, Oncology of the combined company, "Trawsfynydd has a differentiated pipeline and an accomplished leadership team poised to advance their lead programs. With a shared focus on developing best-in-class medicines for patients with unmet needs, we look forward to Traws' continued progress with its anti-viral programs and narazaciclib."

Traws Proprietary Portfolio:

TRX100 (viroksavir): a cap-dependent endonuclease inhibitor for influenza: Phase 1

- Targets the cap-dependent endonuclease of influenza and is a potent inhibitor of influenza virus replication including A and B strains
- Preclinical data showed that TRX100 inhibits viral replication of pandemic-potential influenza viruses circulating in nature during 2022, and importantly, also in oseltamivir and baloxavir-resistant viruses
- Completed a first Phase 1 study that demonstrated safety and tolerability in healthy volunteers. The study also provided pharmacokinetics and pharmacodynamics (PK/PD) data to support the potential use of a single oral dose administration for either treatment or prophylaxis

Next milestones: H2 2024

- Phase 1 dose extension will evaluate two additional, higher doses prior to the initiation of Phase 2 studies in H2 2024. Topline data from the Phase 2 study are expected in H1 2025

TRX01 (travaltrevir): Mpro protease inhibitor for COVID19: Phase 1

- Potent oral inhibitor of SARS-CoV-2 Mpro (3CL protease), effective against the original, delta, and omicron variants of

SARS-CoV-2, with potentially superior properties to nirmatrelvir (Pfizer's Mpro inhibitor, PAXLOVID™)

- Does not require co-administration with a human cytochrome P450 (CYP) inhibitor such as ritonavir, avoiding potential significant drug:drug interactions, with the opportunity to expand the number of eligible patients
- Safe in GLP toxicology studies with no adverse events (AEs) in the expected human dose range. The drug candidate's pharmacokinetic (PK) profile may enable a once-daily 10 day treatment regimen, to reduce the likelihood of viral rebound

Next milestones:

- Phase 1 first-in-human single ascending dose/multiple ascending dose (SAD/MAD) study in normal volunteers initiated screening in Q1 2024. Topline data are expected H2 2024
- Phase 2 study planned to be initiated in H2 2024. The study will enroll people with moderate to severe COVID19. Topline data are expected H1 2025

Narazaciclib: CDK 4/6 inhibitor for LGEEC: Phase 1/2

- Narazaciclib's mechanism of action in LGEEC has been validated by Phase 2 studies with other approved CDK4/6 inhibitors: palbociclib (Pfizer), ribociclib (Novartis), and abemaciclib (Lilly). Available preclinical and clinical data suggest that narazaciclib has the potential to provide a better efficacy/safety ratio compared to approved products with respect to reduced gastrointestinal (GI) and hematological toxicities. These characteristics may permit daily administration with no need for the drug holidays employed by other approved agents to manage severe bone marrow suppression.
- In pre-clinical studies, narazaciclib demonstrated reduced neutropenia compared to palbociclib and inhibited the growth of cancer cell lines resistant to palbociclib
- Currently in Phase 1/2a study to define the RP2D

Next milestone:

- Define the RP2D and development strategy for LGEEC/other indications

Management and Organization

Traws will be led by incoming Chief Executive Officer, Werner Cautreels, Ph.D.; President and Chief Scientific Officer, Oncology, Steven Fruchtman M.D., (Onconova); Chief Financial Officer, Mark Guerin (Onconova), Chief Medical Officer, Robert Redfield, M.D., (Trawsfynydd), Chief Scientific Officer, Virology, C. David Pauza, Ph.D., (Trawsfynydd) and Chief Operating Officer, Nikolay Savchuk, Ph.D., (Trawsfynydd/Torrey Pines), as well as several other members of the Onconova and Trawsfynydd teams.

Traws' Board of Directors will be comprised of Trawsfynydd's Chairman Iain Dukes, DPhil (Venture Partner at OrbiMed), Executive Chairman, Werner Cautreels, Nikolay Savchuk, Ph.D. (General Partner of Torrey Pines) as well as existing Onconova Directors Trafford Clarke, Ph.D, James Marino, J.D. and M. Theresa Shoemaker and Jack E. Stover.

About the Merger and Private Financing

Onconova issued the following in the transactions: in connection with the merger, the stockholders of Traswfynydd received an aggregate of 3,549,538 shares of common stock and 10,359.0916 shares of newly issued Series C non-voting convertible preferred stock (with a conversion ratio of preferred to common at 1:10,000) (the "Series C preferred stock"), and in connection with the private financing, OrbiMed and Torrey Pines received an aggregate of 496,935 shares of common stock and 1,578.2120 shares of Series C preferred stock. This represents, on a fully diluted basis, 75.7% for Trawsfynydd, 13.7% for Onconova and 10.6% for new investors with a combined fully diluted equity value of $132 million (excluding transaction fees). In connection with the transactions, a non-transferrable contingent value right (a "CVR") will be distributed to Onconova stockholders of record as of the close of business on April 15, 2024. Holders of the CVR will be entitled to receive certain proceeds received by Onconova, if any, related to the disposition, net sales or monetization of narazaciclib and rigosertib.

The shares of common stock issuable upon conversion of the Series C preferred stock issued in the Merger and the private financing shall be subject to stockholder approval in compliance with the rules of the NASDAQ Stock Market.

Tungsten Advisors served as the exclusive financial advisor and placement agent to Onconova. Orrick, Herrington & Sutcliffe, LLP and Morgan, Lewis & Bockius LLP are serving as legal counsel to Onconova. Snell & Wilmer L.L.P. is serving as legal counsel to Trawsfynydd.

Webcast Presentation

The companies will host a webcast presentation to discuss the proposed transaction tomorrow, April 2 at 8:30 a.m. ET.

Dial-in details are:

- Investors Dial-in: 1-877-407-0784
- International Investors Dial-in: 1-201-689-8560
- Conference ID: 13745512

Call me™: Participants can use Guest dial-in #s above and be answered by an operator OR click the Call me™ link for instant telephone access to the event.

- https://callme.viavid.com/viavid/?callme=true&passcode=13745512&h=true&info=company-email&r=true&B=6
- Call me™ link will be made active 15 minutes prior to scheduled start time.

Webcast: https://viavid.webcasts.com/starthere.jsp?ei=1663864&tp_key=8103bfd962:

A replay of the webcast will also be available via Onconova's investor website approximately two hours after the call's conclusion.

About Onconova Therapeutics, Inc.

Onconova is a clinical-stage biopharmaceutical company focused on discovering and developing novel products for patients with cancer. Onconova has been focused on developing targeted anti-cancer agents designed to disrupt specific cellular pathways that are important for cancer cell proliferation including the novel, multi-kinase inhibitor narazaciclib, under evaluation for low grade endometroid endometrial cancer (LGEEC).

About Trawsfynydd Therapeutics, Inc.

Trawsfynydd is an antiviral drug development company committed to reducing disease and death among people with respiratory viral diseases including Influenza and COVID19. Trawsfynydd combines excellence in medicinal chemistry with the tools of AI and machine learning, to guide and accelerate the drug development process. We are especially committed to developing best-in-class treatments for the elderly, immunocompromised and other vulnerable populations who are at increased risk for severe disease and death from respiratory virus infections.

About Traws Pharma, Inc.

Traws is developing next-generation, best-in-class antivirals for influenza, COVID and other respiratory infections and narazaciclib. Traws was formed from the business combination of Onconova Therapeutics, Inc. and Trawsfynydd Therapeutics, Inc. and is headquartered in Newtown, PA and will trade on NASDAQ as "TRAW" starting on April 3, 2024.

Forward-Looking Statements

This communication contains "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including but not limited to, express or implied statements regarding the structure, the combined company's listing on Nasdaq; expectations regarding the ownership structure of the combined company; expectations regarding the issuance and value of CVRs; expectations regarding the conversion of the Series C preferred stock and related stockholder approval; expectations regarding the structure, timing and funding of the private placement financing, expected proceeds and impact on ownership structure; each company's and the combined company's expected cash position at the closing of the Merger and the expected cash runway of the combined company following the Merger and private financing; the nature, strategy and focus of the combined company; the development and commercial potential and potential benefits of any product candidates of the combined company; anticipated clinical drug development activities, related timelines and expected milestones; and other statements that are not historical fact. All statements other than statements of historical fact contained in this communication are forward-looking statements. These forward-looking statements are made as of the date they were first issued, and were based on the then-current expectations, estimates, forecasts, and projections, as well as the beliefs and assumptions of management. There can be no assurance that future developments affecting Traws, the Merger or the private placement financing will be those that have been anticipated.

Forward-looking statements are subject to a number of risks and uncertainties, many of which involve factors or circumstances that are beyond Traws' control. Traws' actual results could differ materially from those stated or implied in forward-looking statements due to a number of factors, including but not limited to (i) failure to timely obtain stockholder approval for the transaction, if at all; (ii) uncertainties as to the timing and the funding of the private financing; (iii) risks related to Traws' ability to manage its operating expenses and its expenses associated with the Merger; (iv) unexpected costs, charges or expenses resulting from the transaction; (v) potential adverse reactions or changes to business relationships resulting from the announcement or completion of the Merger; (vi) the uncertainties associated with Traws' product candidates, as well as risks associated with the clinical development and regulatory approval of product candidates, including potential delays in the commencement and completion of clinical trials, studies and evaluations; (vii) risks related to the inability of the combined company to obtain sufficient additional capital to continue to advance these or other product candidates; (viii) uncertainties in obtaining successful clinical results for product candidates and unexpected costs that may result therefrom; (ix) risks related to the failure to realize any value from product candidates currently being developed and anticipated to be developed in light of inherent risks and difficulties involved in successfully bringing product candidates to market; and (x) risks associated with the possible failure to realize certain anticipated benefits of the Merger, including with respect to future financial and operating results. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties. These and other risks and uncertainties are more fully described in periodic filings with the U.S. Securities and Exchange Commission (the "SEC"), including the factors described in the section titled "Risk Factors" in Onconova's Annual Report on Form 10-K for the year ended December 31, 2023, which was filed with the SEC on April 1 2024, subsequent Quarterly Reports on Form 10-Q filed with the SEC, and in other filings that Traws makes and will make with the SEC. You should not place undue reliance on these forward-looking statements, which are made only as of the date hereof or as of the dates indicated in the forward-looking statements. Traws expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in its expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based. This communication does not purport to summarize all of the conditions, risks and other attributes of an investment in Traws.

Company Contacts:
Mark Guerin
Onconova Therapeutics, Inc.
267-759-3680
ir@onconova.us
https://www.onconova.com/contact/

Investor Contact:

Bruce Mackle
LifeSci Advisors, LLC
646-889-1200
bmackle@lifesciadvisors.com