CLARUS THERAPEUTICS AND HAVAH THERAPEUTICS ANNOUNCE LICENSING AGREEMENT FOR PRODUCT TO TREAT ANDROGEN-DEPENDENT INFLAMMATORY BREAST DISEASE AND CERTAIN FORMS OF BREAST CANCER

Agreement aims to accelerate development of a unique testosterone treatment for inflammatory breast diseases and estrogen-receptor positive breast cancer

NORTHBROOK, Ill. and NORTH ADELAIDE, South Australia – May 25, 2021 – Clarus Therapeutics Inc. ("Clarus"), a pharmaceutical company dedicated to providing solutions to unmet medical needs by advancing androgen and metabolic therapies for men and women, and HavaH Therapeutics ("HavaH"), an Australia-based biopharmaceutical company developing androgen therapies for inflammatory breast disease and certain forms of breast cancer by using the innate breast-tissue-specific hormone/immune interface, today announced a licensing agreement whereby Clarus will acquire the exclusive worldwide (excluding Australia) development and commercialization rights for HAVAH T+Ai™ (CLAR-121).

CLAR-121 is a proprietary combination of testosterone (T) (natural ligand for the androgen receptor; AR) and anastrozole (inhibitor of T conversion to estradiol) delivered by a subcutaneous implant for treatment of AR-mediated breast disease that predominantly affects women. If approved, CLAR-121 would be the first T treatment of its kind for inflammatory breast disease, including inflammatory periductal mastitis (PDM), and estrogen receptor-positive (ER+) breast cancer. Clarus's initial clinical development target is PDM — a destructive autoimmune inflammatory process of the retro-areolar milk ducts that results in multiple fistulae and inevitably results in disfiguring surgery and a high risk of recurrence. There is no known treatment for this condition apart from surgery, which has significant limitations.[1] Due to the low prevalence of PDM in the U.S., Clarus anticipates this disease could qualify for orphan drug designation by the U.S. Food and Drug Administration and plans to petition the agency for that status for CLAR-121.

HavaH has extensive clinical experience with CLAR-121 in more than 1,000 Australian women (more than 6,200 implants) with breast disease, and Clarus expects that access to HavaH's pharmacokinetics, safety and early efficacy data in PDM will expedite progression to Phase 2/3 clinical studies in the U.S. Clarus estimates that the annual U.S. market size for PDM exceeds $400 million.[2,3,4] With this new pipeline asset, Clarus may also pursue, alone or in partnership, future indications in ER+ breast cancer, macromastia, granulomatous mastitis, and autoimmune induced breast pain.

"This licensing agreement marks the beginning of an exciting new partnership with HavaH. Their experience coupled with the significant amount of clinical data generated in Australia will benefit Clarus greatly as we begin our development activities in the U.S.," said Dr. Robert Dudley, Clarus's founder, president and CEO. "CLAR-121 allows us to leverage our expertise in androgen biology, as exemplified by JATENZO, a testosterone replacement therapy (TRT) for male hypogonadism and Clarus's first

[1] Zhang, Yanna et al. Clinical characteristics, classification, and surgical treatment of periductal mastitis. J Thorac Dis 2018; 10(4): 2420-2427.
[2] Dixon JM, et al. Periductal mastitis and duct ectasia: different conditions with different aetiologies. Br J Surg 1996; 83: 820-822.
[3] Eberl MM, Phillips RL, Jr., Lamberts, H, et al. Characterizing breast symptoms in family practice. Ann Fam Med 2008; 6(6):528-33.
[4] US Census Bureau, accessed on 06/15/2020: https://ftp.cdc.gov/pub/Health_Statistics/NCHS/NHIS/SHS/2018_SHS_Table_A-18.pdf.

commercial product, and expands our development pipeline with an initial focus on PDM in women — a debilitating, painful disease with very limited treatment options, short of invasive surgery. This treatment, if approved, has the potential to be life-changing for women who suffer from PDM, and its development fits well with our mantra: 'good is never good enough'. Our goal is to provide treatment options that not only produce a positive clinical outcome, but also provide a positive therapeutic experience for patients."

Under the terms of the licensing agreement, Clarus will be responsible for future global development and regulatory activities for CLAR-121, excluding Australia. Clarus will pay HavaH an upfront payment of $500,000 upon signing and HavaH may be eligible for up to $10.75 million in potential development and regulatory milestone payments. HavaH will retain the right to promote HAVAH T+Ai in Australia. Additionally, HavaH would be eligible for a modest royalty and up to $30 million in potential commercial milestones.

"We developed HAVAH T+Ai to address a significant unmet need in women's health, and our partnership with Clarus will enable us to advance this therapeutic approach not only for inflammatory breast disease but, more widely we hope, for ER+ breast cancer where data now unambiguously demonstrates that the androgen receptor has an important tumor suppressor role in this form of breast cancer,"[5] said Stephen Birrell, MD, PhD, HavaH founder, chairman and chief medical officer.

"In Clarus, we found a partner who understands and appreciates the potentially profound importance of androgen action in the context of inflammatory breast disease, as well as its role as an adjunctive endocrine therapy for certain forms of breast cancer," said Kathy Harrison, HavaH CEO.

Reedland Capital Partners, acting through Weild & Co., member FINRA/SIPC, served as financial advisor to HavaH in connection with this transaction. For more information, please visit www.reedland.com.

About Clarus Therapeutics, Inc.

Clarus is a pharmaceutical company with expertise and interest in developing androgen and metabolic therapies for men and women, including potential therapies for orphan indications. Clarus successfully developed and brought to market JATENZO® (testosterone undecanoate oral capsules; CIII) — a new state-of-the-art oral TRT. JATENZO was launched in February 2020 as the first and only FDA-approved oral softgel for TRT in adult males who have low or no testosterone due to certain medical conditions.[6,7,8] For more information, visit www.clarustherapeutics.com and www.JATENZO.com.

[5] Hickey, TE, Selth, LA, Chia, KM, et al. The androgen receptor is a tumor suppressor in estrogen receptor – positive breast cancer. Nat. Med. 2021; 27: 310-320.
[6] JATENZO (testosterone undecanoate) [prescribing information]. Clarus Therapeutics, Inc.
[7] US Food & Drug Administration. FDA Approved Drug Products. Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=206089. Accessed October 1, 2019.
[8] US Food & Drug Administration. NDA Approval Letter. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/206089Orig1s000ltr.pdf

At the end of April, Clarus announced a new chapter for the company as it entered into a definitive business combination agreement with Blue Water Acquisition Corp. (NASDAQ: BLUW) (Blue Water), a special purpose acquisition company (SPAC), that will result in Clarus becoming a publicly traded company when the transaction closes in the third quarter of 2021.

About HavaH Therapeutics

HavaH Therapeutics is an Australia-based women's hormonal health biopharmaceutical company founded in 2005. HavaH's transition into the US market was facilitated by the appointment in 2017 of San Francisco-based Executive Director Ronald Martell.

HavaH is developing innovative, proprietary hormonal therapies that aim to improve quality of life for women across the world. HavaH brings together a world-class team passionate about helping women live lives free from the suffering caused by breast pain, debilitating menopausal symptoms and breast cancer. More information is available at www.havahtx.com

Clarus Forward-Looking Statement

Certain statements in this press release and the information incorporated herein by reference may constitute "forward-looking statements" for purposes of the federal securities laws. 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, including those relating to the success, cost and timing of our product development activities and clinical trials, including our estimates regarding timing to commence future clinical trials, the potential attributes and benefits of our product candidates, the potential attributes and benefits of product candidates, including CLAR-121, our ability to obtain and maintain regulatory approval for our product candidates and our ability to obtain funding for our operations when needed. Forward-looking statements include statements relating to our management team's expectations, hopes, beliefs, intentions or strategies regarding the future. 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. The words "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intends," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "will," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. These forward-looking statements are based on current expectations and beliefs concerning future developments and their potential effects. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described under the heading "Risk Factors" in the preliminary proxy/prospectus for our proposed business combination, and those that are included in any of our future filings with the SEC. Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Some of these risks and uncertainties may in the future be amplified by the COVID-19 pandemic and there may be additional risks that we consider immaterial, or which are unknown. It is not possible to predict or identify all such risks. Our forward-looking statements only speak as of the date they are made, and we do not undertake any obligation to update or revise any forward-

looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

Clarus Investor Relations Contact:
Ric Peterson
Clarus Therapeutics, Inc.
555 Skokie Blvd., Suite 340
Northbrook, IL 60062
(847) 562-4300
rpeterson@clarustherapeutics.com

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About JATENZO

INDICATION
JATENZO (testosterone undecanoate) capsules, CIII, is an androgen indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:

- Primary hypogonadism (congenital or acquired): testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range.
- Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range.

LIMITATION OF USE
Safety and efficacy of JATENZO in males less than 18 years old have not been established.

IMPORTANT SAFETY INFORMATION

WARNING: INCREASES IN BLOOD PRESSURE

- **JATENZO can cause blood pressure (BP) increases that can increase the risk of major adverse cardiovascular events (MACE), including non-fatal myocardial infarction, non-fatal stroke and cardiovascular death.**
- **Before initiating JATENZO, consider the patient's baseline cardiovascular risk and ensure blood pressure is adequately controlled.**
- **Periodically monitor for and treat new-onset hypertension or exacerbations of pre-existing hypertension and re-evaluate whether the benefits of JATENZO outweigh its risks in patients who develop cardiovascular risk factors or cardiovascular disease on treatment.**
- **Due to this risk, use JATENZO only for the treatment of men with hypogonadal conditions associated with structural or genetic etiologies.**

CONTRAINDICATIONS
JATENZO is contraindicated in men with breast cancer or known or suspected prostate cancer. JATENZO is contraindicated in women who are pregnant as testosterone may cause fetal harm.

WARNINGS AND PRECAUTIONS

- Check hematocrit prior to initiation and every 3 months while a patient is on JATENZO and if hematocrit becomes elevated, stop JATENZO until hematocrit decreases to an acceptable level. If hematocrit increases after JATENZO is restarted, stop permanently.
- Monitor patients with benign prostatic hyperplasia (BPH) treated with androgens due to an increased risk for worsening signs and symptoms of BPH.
- Venous thromboembolic events (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE), have been reported in patients using testosterone replacement products like JATENZO. Evaluate patients with signs or symptoms consistent with DVT or PE and, if a VTE is suspected, discontinue JATENZO and initiate appropriate workup and management.
- Testosterone has been subject to abuse, typically at doses higher than recommended for the approved indication and in combination with other anabolic androgenic steroids.
- Large doses of androgens can suppress spermatogenesis by feedback inhibition of pituitary FSH. Inform patients of this risk before prescribing JATENZO.
- Prolonged use of high doses of methyltestosterone has been associated with serious hepatic adverse events. JATENZO is not known to cause these adverse events; however, patients should be instructed to report any signs of hepatic dysfunction and JATENZO should be discontinued while the cause is evaluated.
- Edema, with or without congestive heart failure, may be a serious complication in patients with pre-existing cardiac, renal, or hepatic disease. In addition to discontinuation of the drug, diuretic therapy may be required.
- Gynecomastia may develop and persist in patients being treated for hypogonadism.
- Sleep apnea may occur in some patients, especially those with risk factors such as obesity or chronic lung disease.
- Changes in the serum lipid profile may require dose adjustment of lipid-lowering drugs or discontinuation of testosterone therapy. Monitor the lipid profile periodically, particularly after starting testosterone therapy.
- Use JATENZO with caution in cancer patients at risk of hypercalcemia. Monitor serum calcium concentration regularly during treatment with JATENZO in these patients.
- Androgens, including JATENZO, may decrease concentrations of thyroxine-binding globulin, resulting in decreased total T4 serum concentrations and increased resin uptake of T3 and T4. Free thyroid hormone concentrations remain unchanged, however, and there is no clinical evidence of thyroid dysfunction.
- Depression and suicidal ideation have been reported in patients treated with JATENZO in clinical trials.

ADVERSE EVENTS
The most common adverse events of JATENZO (incidence ≥2%) are headache (5%), increased hematocrit (5%), hypertension (4%), decreased HDL (3%), and nausea (2%).

These are not all the risks associated with JATENZO. For more information, click here for full Prescribing Information, including BOXED WARNING on increases in blood pressure. You can also obtain information regarding JATENZO at www.jatenzo.com.