RACE ONCOLOGY

ASX Announcement

Completion of Bisantrene cGMP API Manufacturing at Laurus Labs

- Laurus Labs (India) completes the large-scale synthesis of 3.25 kg bisantrene dihydrochloride API
- API certified to Good Manufacturing Practice quality standards and suitable for use in humans in all regulatory jurisdictions, including Australia, USA, and the EU
- Innovative processes and discoveries made that support new intellectual property for Race

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27 September 2023 – Race Oncology Limited ("Race") is pleased to announce that Laurus Labs (India) has successfully produced its first batch of bisantrene dihydrochloride, Race's active pharmaceutical ingredient (API), to a standard that meets the quality specified under the 'Code of Good Manufacturing Practice' (cGMP). This 3.25 kg batch was manufactured using an improved process, considered scalable to commercial quantities. Innovations incorporated into the manufacturing will support new Race patent applications.

In Q2 2022, Race announced that it had selected Laurus Labs as its new API manufacturer (ASX Announcement: 21 April 2022). This decision was made to ensure the continuity of supply of bisantrene dihydrochloride API at a scale and quality suitable for use in Race's flagship new drug product, RC220, and support future clinical trial activities.

Transfer of process chemistry know-how from the previous manufacturer to Laurus (i.e. 'tech-transfer') was successfully implemented. Each of the chemistry steps required to synthesise bisantrene dihydrochloride was systematically optimised by Laurus, resulting in greater yields, higher purity intermediates, and ultimately a higher quality, cGMP-certified API. Significant efficiencies were achieved throughout the cGMP campaign, with the innovative chemical processes providing Race with valuable new intellectual property (IP).

Importantly, significant work was undertaken to qualify and quantitate manufacturing process impurities; a requirement to support registration of any bisantrene-containing drug product (such as Race's new bisantrene formulation, RC220) under a US FDA New Drug Application (NDA). While not required for upcoming early-stage clinical trials, meeting this level of cGMP quality assurance demonstrates to potential partners that the bisantrene API can be produced to the exacting standards required later by regulatory agencies before marketing approval.

Executive Director, Dr Pete Smith commented: *"Completion of the first batch of API at our new Contract Manufacturing Organisation (CMO), Laurus Labs, and its certification of cGMP quality, is an important milestone for Race. Laurus Labs has performed very well during this first campaign and has the capabilities and capacity to provide our clinical development and commercial needs for API over the longer term."*

"We have sufficient active pharmaceutical ingredient for our RC220 cGMP drug product manufacturing program and near-term clinical trials. As an unexpected bonus, there have been some discoveries made at Laurus during the manufacturing campaign that can add to our overall intellectual property position. We look forward to continuing our productive relationship with Laurus."

Next Steps

- Transfer and use of the Laurus Labs cGMP-grade bisantrene dihydrochloride to Ardena (Belgium) for use in the manufacturing of RC220 (ASX Announcement: 12 July 2023), Race's new sterile formulation for infusion that will enable safe peripheral IV administration of bisantrene to patients.

- Completion of a package of Phase 3 readiness studies at Laurus Labs.

- Protection of IP assets developed at Laurus Labs and owned by Race.

Q & A

What is the significance of the statement: 'API certified to Good Manufacturing Practice quality standards and suitable for use in humans in all regulatory jurisdictions, including Australia, USA, and the EU'?

A drug product (i.e. a medicine) approved for use in humans will usually contain: (i) an active pharmaceutical ingredient (API) and (ii) excipients. For Race Oncology's new drug product, RC220, the API is bisantrene dihydrochloride. This is the 'drug substance' that produces the pharmacological effect (i.e. anticancer activity). All APIs must be manufactured to cGMP standards. The excipients, or other components present in the drug product, are there to improve the pharmaceutical properties of the formulated API. For example, excipients may be used to prolong shelf-life, modify the drug's solubility, or for other clinically important reasons. As for the API, each of the excipients must also meet stringent cGMP quality standards, as must the final drug products before they can be used in humans.

With Laurus Labs synthesising 3.25 kg of bisantrene dihydrochloride API to cGMP standards, Race now has the chemical material needed to manufacture its bisantrene drug product (RC220) for use in upcoming clinical trials.

What is the commercial importance of achieving greater than early-stage trial cGMP quality?

Large pharmaceutical enterprises looking to partner with or acquire assets from smaller biotech companies will carefully assess risks associated with Chemistry, Manufacturing, and Controls (CMC). CMC is a critical component of the drug development process that ensures stringent quality and consistency standards are met throughout the manufacturing of pharmaceutical products. This ensures that the drug products used in clinical trials are representative of those that later become commercially available. There have been unfortunate examples of large pharmaceutical companies buying new assets from small biotech companies at the Phase 2 or 3 stage, where the clinical data could not be used to support a later NDA application due to earlier CMC inconsistencies/failures. Ensuring that our bisantrene API is manufactured to the highest regulatory standards helps to minimise this risk.

-ENDS-

About Race Oncology (ASX: RAC)

Race Oncology (ASX: RAC) is an ASX-listed clinical stage, global biotechnology company with a dedicated mission to be at the heart of cancer care.

Race's lead asset, bisantrene, is a small molecule anthracene chemotherapeutic. Bisantrene has a unique and rich clinical history with demonstrated therapeutic benefits in both adult and paediatric patients, a well characterised safety profile, and compelling clinical data demonstrating an anti-cancer effect and less cardiotoxicity than other comparable agents.

Race is developing bisantrene to address the high unmet need of patients across multiple oncology indications, with an initial focus on metastatic breast cancer (lead indication) and acute myeloid leukaemia (AML) exploring anti-cancer plus cardio-protection in synergy with known standards of care.

As part of its clinical and preclinical programs, Race is investigating the effect of bisantrene on the m^6A RNA pathway, following independent research by the City of Hope identifying bisantrene as a potent inhibitor of FTO (Fat mass and obesity-associated protein). Dysregulation of the m^6A RNA pathway has been described in numerous peer reviewed studies to be a driver of a diverse range of cancers.

Race Oncology is in collaboration with City of Hope, MD Anderson, Sheba City of Health and UNC School of Medicine, and is actively exploring partnerships, licence agreements or a commercial merger and acquisition to accelerate access to bisantrene for patients with cancer across the world.

Learn more at www.raceoncology.com

If you have any questions on this announcement or any past Race Oncology announcements, please go to the Interactive Announcements page in our Investor Hub https://announcements.raceoncology.com

Race encourages all investors to go paperless by registering their details with the Company's share registry, Automic Registry Services, at www.automicgroup.com.au.

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