

PRESS RELEASE

Oncoheroes out-licences volasertib to US Notable Labs for adult cancers

- Notable will focus on the adult market, while Oncoheroes will continue clinical development of volasertib to treat childhood cancer. The start-up is working with the European Innovative Therapies for Children with Cancer (ITCC) Consortium to begin a phase Ib/II trial to treat paediatric rhabdomyosarcoma, sponsored by the University of Birmingham and funded by Cancer Research UK.
- In 2019, Oncoheroes obtained from Boehringer Ingelheim the exclusive global licence to volasertib for all indications in order to develop it for paediatric oncology use. In 2020, volasertib was awarded Orphan Drug Designation and Rare Paediatric Disease Designation by the FDA to treat paediatric rhabdomyosarcoma.
- Oncoheroes Biosciences Inc. is a biotech start-up co-founded by Catalan entrepreneur Ricardo García and Italian scientist Cesare Spadoni, both fathers affected by childhood cancer. The company is based in Boston (United States) and centralises all its drug discovery at the Barcelona Science Park (PCB).
- Since its incorporation in 2017, Oncoheroes has raised \$8.8 million from private investors, foundations and governmental organisations. Oncoheroes has its own drug discovery lab at the PCB and is about to complete an initial portfolio of four new drug candidates, three of which are ready to enter the clinical phase while it continues scouting for investment. Of the capital raised so far, \$2.9 million is from cancer foundations and/or families affected.

Barcelona, 18 November 2021. [Oncoheroes Biosciences](#), a US-based start-up present at the Barcelona Science Park that focuses exclusively on advancing and developing new therapies for childhood cancer, has out-licensed volasertib's global development and commercialisation rights for cancer in adults to the US biopharmaceutical firm Notable Labs, a pioneer biotech developing preventive and precision medicine. According to the terms of the agreement, the financial details have not been made public. Oncoheroes will retain the global licence to develop and market the drug for paediatric oncology.

[Volasertib](#) is an inhibitor of the kinase PLK-1, an enzyme shown to occur in a wide range of solid tumours and haematological cancers. The compound was discovered and developed by Boehringer Ingelheim for acute myeloid leukaemia (AML). However, the company decided to stop the development of volasertib for strategic reasons after the results of a phase III study in adults did not meet its expectations.

In 2019, Oncoheroes obtained the exclusive global licence of volasertib to continue its clinical development for younger oncology patients. In 2020, volasertib was awarded Orphan Drug Designation (ODD) and [Rare Paediatric Disease Designation](#) (RPDD) by the US Food and Drug Administration (FDA) to treat paediatric rhabdomyosarcoma (RMS), the most common soft tissue sarcoma in children and adolescents.

*“Getting RPDD status for volasertib is an important milestone for Oncoheroes because it means we are eligible for a Priority Review Voucher (PRV) once the drug is approved. Companies holding a PRV can use it at any time to accelerate FDA review of one of their drug candidates, helping them reach the market faster”, explains **Ricardo Garcia**, Oncoheroes founder and CEO. “PRVs are only granted to companies developing drugs for rare or orphan diseases, like Oncoheroes is doing in paediatric oncology. However, companies that are granted with a PRV but do not want to use it are allowed to transfer it. Big pharma companies are very interested in getting them and are willing to pay. The average selling rate for a PRV is \$100 million. Most of the new drugs Oncoheroes is planning to develop are eligible for a PRV”.*

Oncoheroes has started manufacturing volasertib and is now working with the European Innovative Therapies for Children with Cancer (ITCC) Consortium to begin a phase Ib/II trial to treat paediatric rhabdomyosarcoma, sponsored by the University of Birmingham and Cancer Research UK, in 2022.

Committed to childhood cancer

Oncoheroes’ business model is to develop a portfolio of new drug candidates for childhood cancer using three strategies: proprietary R&D, in-licensing drugs in the clinical phase and partnerships with the pharmaceutical industry, academia, hospitals, foundations and patients’ associations.

*“Childhood cancer is not like adult cancer; it requires a different treatment as some of the most devastating childhood cancers only occur in children. Unfortunately, in most cases, paediatric oncologists are forced to adapt adult treatments to the children. Currently, there are only five drugs available that have been developed and approved specifically for childhood cancer, despite being the number one cause of death by disease in children. Moreover, treating children with drugs that were not designed for them, results in more survivors living with lifelong side effects associated with drug toxicity, which in some cases can be very serious”, explains **Cesare Spadoni**, co-founder and COO of Oncoheroes.*

Oncoheroes centralises its global R&D for drug discovery at its lab at the Barcelona Science Park. The centre is led by **Dr. Eva Méndez**, Oncoheroes’ Chief Discovery Officer. Dr. Mendez has over 20 years of experience in academic and industrial biomedical research. *“As far as we know, our lab is the only one in the industry dedicated 100% to discovering new targets, biomarkers and drug candidates for childhood cancer. In 2019, we launched our first drug discovery project, [2HIT-Medulloblastoma](#) to treat paediatric medulloblastoma, the most common brain tumour in children. Our goal is to select and characterise a preclinical candidate that will be ready to enter the regulatory preclinical phase by the end of 2023. The lab was initially funded through Neotec, ENISA, Torres Quevedo and Industrial Doctorates non dilutive funds”, notes **Dr. Eva Méndez**.*

Its determination and exclusive commitment to childhood cancer has led Oncoheroes to design a strategy that will allow the company to continue funding its growing portfolio by out-licensing some of its drug candidates for the adult market. *“Volasertib’s out-licence for adults not only reaffirms our solely focus on childhood cancer but also validates one of the business model. The potential approval of volasertib for the adult cancer market by Notable would bring in revenue to Oncoheroes for milestones and royalties, which we can re-invest to develop new drugs for childhood cancer”, says **Ricardo García**.*

To date, Oncoheroes has raised \$8.8 million from private investors, foundations and governmental organisations. This capital has allowed the company to set up its drug discovery lab at the Barcelona Science Park and to continue advancing development of its first two assets (volasertib and the 2HIT Medulloblastoma project). *“Furthermore”, adds **Ricardo**, “we are working to incorporate two assets that are closer to entering the clinical phase to complete our portfolio”.*

Active role of foundations and affected families

To date, \$2.9 million of the capital raised by Oncoheroes comes from cancer foundations and/or families affected. *“14 non-profit organisations have invested in our project. They are organizations that have supported childhood cancer research for the past 40 years with more than \$300 million. For many of them, this is the first time they have invested in a biotech company. We are optimistic that with the progress we have shown so far, most will invest again, as [we saw recently](#) with the first childhood cancer foundation that invested in Oncoheroes, the [Andrew McDonough B+ Foundation](#)”, highlights the co-founder of Oncoheroes.*

In September 2021, Oncoheroes [announced](#) an investment from Fundación Olivares, a non-profit organisation to fight childhood cancer based in Málaga (Spain). It was the first time this organisation decided to support childhood cancer research and invested in a biotech company.

*“Before Fundación Olivares, Oncoheroes received investment from several US childhood cancer foundations, some considered global references in funding research. We’ve very excited to be working with the first Spanish childhood cancer organisation to join our project”, concludes **Ricardo García**.*

■ Oncoheroes Biosciences Inc.

Oncoheroes Biosciences (oncoheroes.com) is a ground-breaking biotech company exclusively focused on the discovery and development of better drugs for children and adolescents with cancer. Our vision is to deliver benefits to young cancer patients and create value in the process. The company headquarters are in Boston (United States) and its European subsidiary is located at the Barcelona Science Park, where it also has a drug discovery lab.

One of the strengths of Oncoheroes is the professional experience and commitment of its founders: [Ricardo García](#) is a serial entrepreneur born in Barcelona. He moved to Boston in 2011 to seek treatment for his six-year-old son Richi diagnosed with medulloblastoma. Today Richi is an adolescent cancer survivor living with a long list of side effects. The other co-founder, [Cesare Spadoni](#), lost his daughter Laura after she was diagnosed with neuroendocrine carcinoma at age three. This type of cancer is relatively rare in children and there are no treatment options.

The team is rounded out with R&D experts and industry professionals from the United States and Europe with over 20 years of experience in drug discovery and development. The company has forged strong ties with the main international networks in paediatric oncology and the global childhood cancer community.

Oncoheroes aims to become the global leader in new drugs for childhood cancer. The company is currently actively seeking opportunities to obtain licences in paediatric oncology and is working to create new patented compounds for a series of paediatric cancer indications that pose a great unmet medical need.

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