

Antibody milestone

Brazilian company licenses molecule with potential to treat cancer

Recepta Biopharma, a Brazilian company based in São Paulo, recently signed an agreement with Mersana Therapeutics of the U.S. to license a monoclonal antibody that could be used in cancer treatments. Under the terms of the partnership, Recepta will cede the rights to the antibody outside of Brazil to Mersana, which the company will use to develop an immunconjugate compound against several tumor targets. Recepta will retain the rights in Brazil. Mersana owns a technology known as Fleximer, which is able to create a so-called ADC (antibody-drug conjugate). “They use a binder to join the antibody to a toxin. This immunconjugate delivers the toxin to the tumor cells in a very targeted way,” says José Fernando Perez, a physicist and the president of Recepta. “We are excited about developing this new immunconjugate to address the unmet needs of cancer patients,” said Anna Protopapas, the president of Mersana, in a press release.

The terms of the agreement provide that Recepta will be entitled to cash payments, provided that predetermined milestones are achieved in development, as well as in regulatory approval and marketing of the drug. It is estimated

that these payments could reach \$86 million. The agreement is unprecedented in Brazil. “It’s the first time a Brazilian biotech company has licensed intellectual property for the development of a potential cancer drug,” says Perez, who was the scientific director of FAPESP from 1993 to 2005. “It shows that bolder things can be done despite the difficulties of conducting drug research in Brazil.”

An antibody is an organism’s defense molecule that specifically binds to its target. A monoclonal antibody is derived from a cell clone and hence all molecules are identical and directed toward the same target. Recepta is working on the development of various monoclonal antibodies, most of them discovered by the Ludwig Institute for Cancer Research, a non-profit organization based in New York, with which the company has partnered. The name of the antibody licensed to Mersana will not be released until the end of the year.

“Recepta showed that it is possible to move ahead in expanding radical innovation such as developing new molecules,” says Carlos Gadelha, an economist and the Secretary of Production Development of the Ministry of Development,

Industry and Foreign Trade (MDIC). He believes that Brazilian biotechnology companies mostly invest in innovation incrementally, merely improving upon known methods and technologies. “The fact that Recepta has transferred knowledge to a U.S. company represents a milestone in Brazil,” says Gadelha, who between 2011 and 2014 was Secretary of Science, Technology and Strategic Inputs of the Ministry of Health.

Perez says that Recepta’s work was facilitated by an environment favorable to providing government resources.

Clinical analysis and production of monoclonal antibodies in the laboratory





FAPESP and the Brazilian Innovation Agency (FINEP) assisted in equipment purchases and supported the work of institutional research groups. The Brazilian Development Bank (BNDES), which has been one of its partners since 2012, also invested in the company. “This is an example of how a long-term strategic alliance between the private sector and federal and state governments can be consolidated,” says Gadelha. José Gomes Temperão, former health minister and current director of the South American Institute of Government in Health (IS-AGS) of the Union of South American Nations (Unasur), believes Recepta’s development of monoclonal antibodies may also represent a breakthrough for Brazil’s industrial health complex. “Get-

ting this product to market will take a long time. But once this is achieved, the focus will be on making this new technology available to all Brazilians, without limitation, through the Unified Health System,” he says.

Ruy de Quadros Carvalho, a researcher at the Department of Science and Technological Policy of the Institute of Geosciences at the University of Campinas (Unicamp), says that Recepta’s example demonstrates the feasibility of distributing the innovation process over an external network of partners, where there is room for universities and partners, whether nearby or with other countries, to help each other according to their expertise. “By licensing the use of monoclonal antibodies, Recepta is

enabling another company to accelerate the development of a new drug, since Mersana has mastered a technology required for this process,” says Quadros.

LINES

An association with research organizations in the state of São Paulo has been decisive when it comes to the monoclonal antibodies developed by Recepta (see *Pesquisa FAPESP Issue No. 223*). With support from FAPESP, Recepta mobilized institutions such as the Butantan Institute and the University of São Paulo School of Medicine (FMUSP), which participated collaboratively at various stages of these studies. Thus, among other advances, it was possible to master one of the monoclonal antibody production stages: obtaining cell lines capable of producing antibodies in large amounts and with the same standard of quality and stability for use in humans. “We have been producing monoclonal antibodies for therapeutic use for over 20 years. We have already developed, for example, a treatment for the rejection of transplanted organs,” says Jorge Kalil, director of the Butantan Institute. He says the partnership with Recepta has been very beneficial to the research institution. “We intend to use the human monoclonal antibody technique in other areas, such as antibodies for tetanus or against some spider venoms,” says Kalil.

Perez, of Recepta, also points out the importance of the company’s translational research activity in collaboration with research groups, such as clinical pathology led by Venâncio Alves and experimental oncology coordinated by Roger Chammas, both professors at FMUSP. “Besides the technological fruits, scientific publications in reference journals in the field were also generated,” he says. ■

Bruno de Piero

Projects

1. *Cell lines with high productivity and stability for humanized monoclonal antibodies for cancer therapy* (No. 2005/60816-8); **Grant Mechanism:** Research Partnership for Technological Innovation (PITE); **Principal Investigator:** Ana Maria Moro (Butantan Institute); **Investment:** R\$377,708.00 and \$810,616.85 (FAPESP), R\$1,793,198.00 (Recepta).

2. *Monoclonal antibodies for treating tumors of the central nervous system* (No. 2008/57914-6 and 2011/50526-3); **Grant Mechanism:** Innovative Research in Small Businesses Program (PIPE); **Principal Investigator:** Maria Carolina Braga Tuma (Recepta); **Investment:** R\$124,788.20 (Phase 1) and R\$456,631.34 (Phase 2).