IN brief

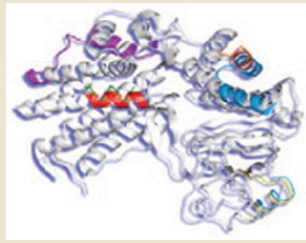
Ablynx drops lead nanobody

Ablynx has discontinued clinical development of its most advanced nanobody citing market reasons. The Ghent, Belgium–based biotech announced in November that ALX-0081—a bivalent nanobody designed to prevent unwanted thrombus formation—did not significantly reduce the number of bleeding events in a phase 2 study treating acute coronary syndrome (ACS) patients compared with approved antithrombic ReoPro (abciximab). ALX-0081 interferes with von Willebrand factor, which acts early in the coagulation cascade. The decision to cut trials short was financial, says Ablynx's CEO Edwin Moses. "The antithrombotics market has become more competitive. Unless you have a standout advantage, it's going to be an uphill commercial battle." The trial wasn't a total waste, as the company plans to channel its efforts into developing the nanobody to treat thrombotic thrombocytopenic purpura (TTP), a rare blood clotting disorder. "It's a sensible decision," comments Mick Cooper, a healthcare analyst at London-based Edison Investment Research. The company will apply the data from the ACS trial to TTP clinical trials, says Moses. The company has two other nanobody drug candidates, ATN-103 and ALX-0061 to treat rheumatoid arthritis, in phase 2. Phase 1 data for ALX-0061, also announced in November, were "very impressive," says Cooper. "The company is doing a very good job of running its clinical programs." **Gunjan Sinha**

India's innovation czar

The Indian government on November 24 approved the creation of a not-for-profit company dedicated to enhancing innovation within the biotech industry, with the focus particularly on small and medium-sized enterprises. The Biotechnology Industry Research Assistance Council (BIRAC) will run as an autonomous body dispensing funding to support industry schemes, previously under the government's Department of Biotechnology (DBT). "Government departments are constrained by bureaucracy," Subbarao Natesh, a senior official in DBT told *Nature Biotechnology*, justifying the need for a separate body outside DBT. BIRAC will function as a single agency for rendering services to the emerging biotech companies and as DBT's long arm supporting industry–academia interaction, he said. BIRAC's mandate "includes technology acquisition and transfers and promoting biotech incubators and biotech parks—in fact the whole ecosystem of innovation," says Renu Swarup in charge of DBT's division that funds discovery projects in the industry. The company is expected to be operational by April 2012. The government has approved an initial core budget Rs.700 ($13.3) million for setting up the company, and DBT's spending on industry innovation schemes—Rs.1.8 billion ($34.3 million) in 2011—will now be diverted to the BIRAC. As a not-for-profit company, BIRAC will be eligible to receive donations. "It is an excellent move," says Villoo Morawala Patell, managing director of Avesthagen, a Bangalore-based biotech firm. **Killugudi Jayaraman**

Toll-like receptor blocker slows beta cell death in type 1 diabetes



Andromeda Biotech

Synthetic peptide DiaPep277

Prospects for Israeli company Andromeda Biotech were bolstered late last year with the news that its synthetic peptide, DiaPep277, had met its primary and secondary end points in a phase 3 trial in type 1 diabetes. DiaPep277 represents a novel approach in diabetes treatment and, as a 24-amino-acid peptide fragment of heat shock protein 60 (Hsp60), is thought to promote the involvement of T regulatory (Treg) cells, with a shift in T helper (Th)1 to Th2 responses. The phase 3 data included 457 newly diagnosed individuals followed over two years. Those in the treatment arm receiving DiaPep277 subcutaneously, on top of their regular insulin injections, maintained adequate diabetic control assessed by C-peptide levels, a marker of endogenous insulin secretion by pancreatic cells and the primary end point for this study.

The news is particularly welcome after the recent failures of two phase 3 trials of humanized monoclonal antibodies (mAbs) aimed at arresting islet-destroying T cells, which have been a blow to the field (*Nat. Biotechnol.* **29**, 782–785, 2011). To complicate matters, the number of type 1 diabetes cases is on the rise. "Studies from Europe have highlighted the increase, particularly in young children," notes Yale University's Kevan Herold.

Several groups are pursuing immunotherapeutic strategies. "This is a very active field," says Mark Peakman, of King's College London. "We know a lot about the cells involved and how the damage occurs." Immunotherapy can focus either on suppressing the autoreactive T cells in the immune system or modulating natural pathways to slow beta cell destruction. DiaPep277 falls into the latter category, which Peakman believes has a better safety profile.

DiaPep277 is based on research by Irun Cohen at the Weizmann Institute in Rehovot, Israel. When investigating diabetic mice, Cohen showed that Hsp60 can prompt an autoimmune attack, whereas injecting a small fragment of Hsp60 shuts down the immune response and prevents type 1 diabetes onset. The peptide was originally produced by Israeli company Peptor and its successor DeveloGen, which merged with Peptor in 2003, and Evotec, which bought DevelopGen last year. Aventis, now Sanofi, licensed and developed the drug in 2002. In 2007, however, the French pharma returned the rights, which were then acquired by Andromeda, a fully owned subsidiary of Clal Biotechnology Industries based in Ramat Gan. Andromeda is partnered with Teva Pharmaceutical Industries based in Petach Tikva, Israel, which is financing DiaPep277's development in return for exclusive marketing rights.

DiaPep277 targets toll-like receptor (TLR)-2 and the T-cell receptor. Heat shock proteins bind TLR-2, inducing noninflammatory regulatory T cells, but can also bind TLR4, inducing a predominantly pro-inflammatory response and potentially promoting autoimmunity. As DiaPep277 lacks the TLR-4 binding sequence of Hsp60, it only induces the noninflammatory pathway. "Our goal is to manipulate the immune system and produce Treg cells," says Shlomo Dagan, Andromeda's CEO. "The compound does not regenerate islet beta cells. We are concentrating on using DiaPep277 to prevent, or block development of, the disease."

Apart from the primary end point of C-peptide, other end points included glycosylated hemoglobin (HbA1c), insulin requirements and several hypoglycemic events. More patients in the treatment group kept to their target HbA1c. No major differences in drug-related adverse events were seen between the two groups. "The new findings from the DiaPep phase 3 study are important," says Herold, noting that once the data are released, it will be critical to see whether the treatment group had reduced insulin requirements and any sign of long-term complications.

Herold has been working with teplizumab, a humanized mAb against CD3 on T cells from Macrogenics, and the next most advanced treatment for type 1 diabetes. Although he describes data from two recently completed phase 2/3 trials as "very encouraging," another anti-CD3 mAb, otelixizumab, recently failed in trials, as did Diamyd, a recombinant glutamic acid decarboxylase vaccine-based strategy.

Andromeda has a confirmatory phase 3 trial planned. "Having a preventative therapy for those who have not yet developed symptoms is very important," says Dagan. "The long-term effects of these drugs is not clear, but even the delay in progression of the disease for two years would be of clinical importance for certain age groups, such as children," adds Herold.

Susan Aldridge, *London*

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