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Antibody R&D: What APAC firms are working on?

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Milestones in antibodies research in APAC

Over the years, some of the Asian companies have made significant breakthroughs in antibody research and are exploring further avenues to enrich their pipeline of products. The developments are significant even in the world market. BioSpectrum gives an overview of the major developments in the field:

Rabbit monoclonal antibody
Taiwan-based Abnova has integrated a high throughput platform for generation of rabbit monoclonal antibody. Conventional

rabbit monoclonal antibody technology uses myeloma fusion for screening of rabbit monoclone hybridoma. This methodology has a narrow antibody repertoire and poor yield of antibody secretion from rabbit hybridoma. Abnova uses a non-fusion antibody library to screen for a greater number of clones of highest affinity and exquisite specificity. The selected clone is introduced into a proprietary expression vector for transient and scalable antibody production for many downstream applications.

According to the company, technology accessibility, intellectual property and higher costs have long hampered a widespread adoption and application of the rabbit monoclonal antibody. Removal of this barrier is critical to the success of proteomics and the biotech industry where traditional antibody tools, such as mouse monoclonal antibody and rabbit polyclonal antibody, face limitations.

CD19 (Human) Matched Antibody Pair, CEBPA (Human) Recombinant Protein (P01), ERCC8 (Human) Recombinant Protein (P01), GZMB (Human) Recombinant Protein (P03) and KRT15 (Human) Recombinant Protein (P02) are some of the antibodies developed by Abnova.

Human antibodies for cancer
Australia-based Patrys, a clinical stage biopharmaceutical company, has developed PAT-SM6, a natural human antibody, that has shown promise as a potential treatment for multiple types of cancer, including melanoma. Patrys was recently granted a US patent for its lead antibody product till at least 2024.

Patrys has completed the phase I trial of PAT-SM6 and is focusing on the development of a completely new type of therapy for the treatment of cancer. These natural human antibodies offer the promise of increased potency coupled with greater safety as compared to existing cancer treatments. It targets an important protein on the surface of cancer cells called GRP78 that plays a number of key roles in cancer cell survival, growth and metastasis. Traditionally, researchers have utilized rodents to generate antibodies that attack human cancer tissues. In most cases, researchers alter the non-human antibodies by adding human components.

Patrys' another leading candidate PAT-SC1, ImmunoglobulinM (IgM) for gastric cancer, is at a mature stage. PAT-SC1 treated gastric cancer patients with a significant 10-year survival and is now at the stage of commercial production, exhibiting its promises towards a second human clinical trial for the treatment of cancer.

Biosimilar antibody
Remsima (infliximab) is a monoclonal antibody against tumor necrosis factor alpha (TNF-Î±) to treat autoimmune diseases developed by Korea-based Celltrion. Approved by the KFDA, Remsima is the world's first antibody biosimilar to receive regulatory approval based on global clinical trials.

Remsima is indicated for rheumatoid arthritis, ankylosing spondylitis, ulcerative colitis, Crohn's disease and psoriatic arthritis. Celltrion has submitted its marketing authorization application (MAA) for Remsima to the EMA and is expecting approval and launch in over 100 countries worldwide. Celltrion expects to receive marketing approval in numerous emerging market countries towards the end of 2012. The company believes that this approval can grant access to $24 billion TNF-Î± antagonist market and is likely to be the only biosimilar that can target the global market for the next five years.

Similarly, India-based Reliance Life Science is advancing its biosimilars portfolio, which includes a number of monoclonal antibodies. The company is currently in discussions with several companies for licensing these products in various geographies. The antibodies developed by RLS are largely in two therapeutic categories: anti-cancer and anti-inflammatory segments.

Anti-CD19 monoclonal antibody
Novel biologics entity GBR 401 is an anti-CD19 monoclonal antibody developed by Glenmark Pharmaceuticals targeting Lymphomas and Leukemia's of B-cell origin. Lymphomas are cancers originating from the lymphatic system. CD19 also holds target potential for treatment of inflammatory disorders, such as rheumatoid arthritis.

Glenmark hopes to emerge GBR 401 as a valuable therapeutic option to treat patients affected with B-cell malignancies. GBR 401 has demonstrated strong anti-tumour potency and anti-proliferative apoptotic activity in several in-vitro and in-vivo studies. Glenmark is pursuing further development of GBR 401 to accelerate its entry into clinical stage. Antibody inhibitors or cytotoxic antibodies against CD19 have the potential to treat B cell or antibody-mediated diseases, including malignancies

and autoimmune diseases. CD19 forms part of the B cell co-receptor in conjunction with CD81 and CD21.

Human anti-angiogenic monoclonal antibody

PharmAbcine, a spin-off company from Korea Research Institute of Bioscience and Biotechnology, is developing Tanibirumab (TTAC-0001), a fully human anti-angiogenic monoclonal antibody against VEGFR-2. The antibody has shown potent anti-angiogenic efficacy against various cancer-involved experiments as well as cross-species cross reactivity in mouse model.

Tanibirumab is in phase I stage with 5th cohort patients. The company will possibly complete its phase I within this year or early next year. PharmAbcine believes that characteristics of Tanibirumab hold reasonable promise of being successful as therapeutics.