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Innovative products for CAR T cell manufacturing

Cell-culture and cell-isolation company STEMCELL Technologies is seeking biotech partners to develop its CAR T cell products for clinical use

n 2013, when researchers announced the successful use of genetically modified T cells expressing a chimeric antigen receptor (CAR T cells) to treat advanced acute lymphocytic leukemia, the field of cancer immunotherapy was electrified. What immediately followed was a tidal wave of activity that included academic labs, big pharma and a host of biotech startups aiming to further develop this type of therapy.

The goal is now to commercialize the production of CAR T cells to make the cell therapy available and affordable. To do that, researchers need reliable products and services to support their work as they move toward clinical trials in the race to develop the first-to-market CAR T cell immunotherapeutic.

Enter STEMCELL Technologies, a 22-year veteran in developing specialized cell-culture media and cell-isolation products for life science research. STEMCELL is a private company with over 650 employees, and as the name implies, STEMCELL's initial products supported stem cell research. Over time, founder, president and CEO Allen Eaves has led the company in expanding its portfolio to encompass more than 2,000 products, including cell-culture media, cell-isolation reagents and other supporting materials.

Now the company is launching new products designed to enable research on and development of CAR T cell therapies (Fig. 1). "The products that we are offering are based on technologies and expertise that we have been developing for over 20 years," said Eaves. "CAR T cell immunotherapy is one of the hottest fields in cancer research right now, and we are providing the tools needed to advance this research and these new therapies."

Launching new products

Building on its history of providing high-quality and consistent reagents, STEMCELL has developed a new line of products for use in the CAR T cell field. "Over the years, we have invested in the development of core technologies that have resulted in the commercialization of a diverse portfolio of products that help streamline the CAR T cell manufacturing workflow," said Terry Thomas, senior VP of R&D at STEMCELL.

These new products for isolating and activating T cells are based on the company's proprietary tetrameric antibody complex (TAC) technology, which has long been used in its column-free EasySep immunomagnetic cell-isolation products. The next generation of patent-pending EasySep technology, featuring Releasable RapidSpheres, provides a no-wash, no-incubation magnetic particle release following the positive



Figure 1: Proposed workflow for the manufacture of CAR T cells using STEMCELL's products.

selection of T cells. This easily scalable T cellisolation platform allows for integration into any CAR T cell manufacturing workflow. Once isolated, T cells are activated using ImmunoCult Human T Cell Activator, a reagent also based on STEMCELL's TAC technology.

This soluble, highly shelf-stable TAC reagent provides robust T cell expansion and has generated much interest among developers of CAR T cell immunotherapies, as it is not yet an exclusively licensed technology. Genetically modified CAR T cells can then be expanded in culture with STEMCELL's xeno-free and serumfree ImmunoCult-XF T Cell Expansion Medium. Together, these new products support the isolation, activation and expansion of T cells with performance equivalent to that of conventional methods using bead-based activation reagents and serum-supplemented culture media.

"The development of STEMCELL's fast, scalable and reliable products for CAR T cell manufacturing promotes a streamlined and optimized workflow for researchers to achieve successful results in this ultra-competitive environment," said Andy Kokaji, senior scientist and leader of STEMCELL's CAR T cell initiative.

Not only do these products fit seamlessly into the workflow for CAR T cell manufacturing, but they also can be customized for other areas. This flexibility speaks to STEMCELL's long history of collaborating with partners and providing quality products that fill gaps in emerging fields.

Poised for partnerships

STEMCELL's new technologies for T cell isolation, activation and expansion are available for purchase and research use. Beyond the bench, STEMCELL, which holds an ISO 13485 certification, is seeking biotech partners to develop products for clinical use. The company currently supports a variety of STEMCELL products used as ancillary materials in more than 20 clinical trials approved under investigational new drug (IND) applications or equivalents. STEMCELL has a robust management program to support these types of partnerships: a dedicated project manager serves as the liaison to the partner and offers a high level of service to ensure that schedules are met and the project meets its deliverables.

"We are uniquely poised to facilitate the development of cell therapies with our technology. We have been in this market for a long time, and many of our products are considered the gold standard," said Eaves. "By enabling our customers to do research, knowing they can count on the quality and consistency of our products, we truly consider ourselves to be scientists helping scientists."

STEMCELL representatives will be attending the BIO International Convention in Philadelphia, Pennsylvania, in June 2015, as well as Bio-Europe in Munich, Germany, in November 2015.

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