

EDGE

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weight and maximum comfort,” added Davood Tashayyod, FNIR Devices CEO. “FNIR Devices systems are very easy to set up and very comfortable for the subject. A comfortable subject produces better-quality data and can participate in short- and long-term studies.”

A gene expression kit using upcyte hepatocytes

STATE COLLEGE, Pa.—INDIGO Biosciences Inc., an industry leader in nuclear receptor research, has announced the addition of a gene expression assay kit featuring upcyte hepatocytes to its portfolio. This addition both complements INDIGO’s industry-leading nuclear receptor assays and meets the demand for an expansion of the portfolio to include methods for researchers to perform the next steps of discovery research in their own laboratories.

While primary hepatocytes have historically been the preferred *in-vitro* model for assessing drug-induced expression of drug metabolizing enzymes, their limited supply from any one donor and their finite lifespan pose a challenge for their routine use. INDIGO’s assay kit utilizes optimized upcyte hepatocytes, which are human donor-derived hepatocytes established by upcyte technologies GmbH. The upcyte hepatocytes combine the characteristics and advantages of primary hepatocytes with the added practical advan-

tage of having access to the same donor cells for use in iterative, large-scale testing over extended periods.

“The addition of the assay kit ... to our portfolio represents a significant expansion in drug discovery capabilities. INDIGO is excited to meet the increasing industry need for extended assay platforms for pre-clinical research,” said Dr. Jack Vanden Heuvel, chief scientific officer of INDIGO.

Ablexis announces licensing deal with Allogene

SAN DIEGO—In December, Ablexis LLC, a biopharmaceutical company focused on licensing its AlivaMab Mouse technology for antibody drug discovery, announced a license agreement with Allogene Therapeutics Inc. The license grants Allogene rights to research, develop and commercialize certain AlivaMab antibodies against several targets. Financial terms were not disclosed.

“Ablexis is excited to add Allogene Therapeutics, a clinical-stage biotechnology company pioneering the development of allogeneic CAR T (AlloCAR T) therapies for cancer, as a licensee,” noted Dr. Larry Green, CEO of Ablexis. “This agreement with Allogene highlights the potential applications of AlivaMab antibodies in novel drug modalities such as CAR Ts. We believe our transgenic mouse platform will play an integral role in the continued advancement of the field of immunotherapy.”

The AlivaMab Mouse is designed to

enable and optimize the efficient discovery and development of the next generation of human therapeutic antibodies. The platform has been validated for antibody drug discovery by Ablexis and partners in various formats including regular antibodies, bispecifics and CAR Ts, and for a range of applications.

Collaboration to offer large-scale genomic analysis tools

PARIS—IntegraGen, a company specializing in the decoding of the human genome with a focus on producing interpretable genomic analysis for academic and private laboratories, announced in late 2018 it will be collaborating with Google Cloud for the implementation of IntegraGen’s advanced genomic analysis tools, SIRIUS and MERCURY, into the Google Cloud Platform. This partnership will enable widespread online availability, rapid data transfer and enhanced data security to clinicians and researchers utilizing these analytical tools.

“Working with Google Cloud will enable us to provide our customers with integrated and powerful options for rapidly analyzing large-scale genomic data online through our SIRIUS and MERCURY analysis tools,” said Bérengère Génin, IntegraGen’s director of bioinformatics. “As was presented during the Paris Google Cloud Summit this past June, the availability of our genomic data analysis tools via the cloud now makes personalized medicine a reality.” ■

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patients with DCM. During the period leading up to the end of the research term, it was important for MyoKardia to maintain 100 percent of the U.S. commercial rights for mavacamten in HCM as well as additional

“Regaining worldwide rights enables us to capture the full value of the data being generated in the next 12 to 24 months as we prepare for the potential registration of mavacamten in obstructive hypertrophic cardiomyopathy and obtain proof-of-concept for MYK-491 in patients with dilated cardiomyopathy.”

Tassos Gianakakos, CEO of MyoKardia

rights in expanded indications. Sanofi subsequently provided MyoKardia with notification of its decision to conclude the collaboration in conjunction with the end of the research term. ■

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**DDNEWS
EDITCONNECT:**

Appearing as an online-only extra this issue is a Patent Docs column by Kevin Noonan about a recent “ray of hope” in patenting. You can find the article by going to www.ddn-news.com and entering the Editconnect number E011931 in the “search our archives” field at the top of the home page.

PARP

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The company is maintaining its guidance for full-year 2018 adjusted earnings per share growth at 8 to 10 percent at CER and expects no change to its dividend policy.

“The acquisition of TESARO will strengthen our pharmaceuticals business by accelerating the build of our oncology pipeline and commercial footprint, along with providing access to new scientific capabilities,” Emma Walmsley, CEO of GSK, said in a press release. “This combination will support our aim to deliver long-term sustainable growth and is consistent with our capital allocation priorities. We look forward to working with TESARO’s talented team to bring valuable new medicines to patients.”

Lonnie Moulder, CEO of TESARO, added: “This transaction marks the beginning of a new global partnership that will accelerate our oncology business and allow our mission of delivering transformative products to individuals living with cancer to endure. Our board and management team are very pleased to announce this transaction, and we are grateful to the management team at GSK for their tremendous vision and the opportunity to preserve and build upon the impact we have had in the cancer community to date.”

While no details were released as to the future of TESARO’s employees or facilities, a GSK press release noted that “GSK is in discussions with several key executives of TESARO to ensure their continued employment with the company.”

TESARO’s lead product is Zejula (niraparib), an oral poly-ADP ribose polymerase (PARP) inhibitor approved for the treatment of ovarian cancer. This drug class has been gaining popularity in ovarian and breast cancer for the benefit seen in women with and without germline mutations in a BRCA gene. Zejula has FDA and EMA approval for adult patients with recurrent ovarian cancer who are in response to platinum-based chemotherapy, regardless of BRCA



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mutation or biomarker status. The drug is also in clinical trials to evaluate it as a monotherapy and part of a combination regimen as a first-line maintenance treatment for ovarian cancer, with results expected in H1 2019.

Some of the other big names in this field at present are Clovis Oncology’s Rubraca and Pfizer’s Talzenna. Leerink Partners commented on the TESARO acquisition, saying “We see this long-awaited acquisition as validating for the PARP inhibitor class. We see shares of [Clovis Oncology], as the most prominent and advanced free-standing PARP, as likely to benefit from improved investor sentiment, particularly given the disparity between the [TESARO] acquisition price and [Clovis Oncology’s] current market capitalization of ~\$1bn.”

George Budwell of The Motley Fool noted

that Clovis shares likely rose after the Tesaro deal because “Investors appear to be betting that Clovis will be the next PARP developer to catch the eye of a deep-pocketed big pharma or blue-chip biotech.”

GSK’s shareholders weren’t wholly sold on the deal, as Budwell pointed out that shares dropped almost 8 percent on Dec. 3 when the news broke. And despite the promise of this drug class, given the return on investment of Zejula and Rubraca—which brought in \$63 million and \$22.8 million, respectively, for the third quarter of 2018—Budwell says that “Glaxo may have just grossly overpaid for Tesaro.”

“On the bright side, Zejula still has a shot at living up to these lofty sales projections over the long run,” Budwell continues. “This drug, after all, is presently in a host of clinical trials for other high-value indications, such as breast and prostate cancer. The downside, though, is that Clovis’ drug is also pursuing similar indications in its clinical program. So there’s a good chance that these two PARP inhibitors will end up competing for market share across many of the same indications. Glaxo, therefore, will need some luck going forward to ensure that this deal turns into a net positive for shareholders and not a costly misstep.”

Hal Barron, chief scientific officer and president of R&D at GSK, said: “Our strong belief is that PARP inhibitors are important medicines that have been under-appreciated in terms of the impact they can have on cancer patients. We are optimistic that Zejula will demonstrate benefit in patients with ovarian cancer beyond those who are BRCA-positive as front-line treatment. We are also very excited that through this transaction, we will have the opportunity to work with an outstanding Boston-based oncology group with deep clinical development expertise, and together we will explore Zejula’s efficacy beyond ovarian cancer into multiple tumor types to help many more patients.” ■

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