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Industry News

Industry Updates from the Field of Stem Cell Research and Regenerative Medicine in June 2019

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Abstract

The latest developments in the field of stem cell research and regenerative medicine compiled from publicly available information and press releases from nonacademic institutions in June 2019.

Keywords:: industry regenerative medicine stem cells

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Business development

announced their collaboration with FluidForm (MA, USA; www.fluidform3d.com), an innovator in 3D bioprinting [1]. FluidForm's FRESH printing technique enables 3D printing of bioinks and other soft materials. Together, Aleph Objects and FluidForm will combine their expertise to offer new bioprinting solutions.

Collaboration agreement: Bioventus & MTF Biologics

Bioventus (NC, USA; www.bioventusglobal.com) has entered into a development collaboration agreement with Musculoskeletal Transplant Foundation, also known as MTF Biologics (NJ, USA; www.mtfbiologics.org), to co-develop a next-generation placental tissue product for the treatment of painful musculoskeletal conditions, with an initial focus on knee osteoarthritis. Terms of the agreement were not disclosed [2].

Collaboration agreement: Emulate & INTENZE

Emulate (MA, USA; www.emulatebio.com) and INTENZE Products (NV, USA; www.intenzetattooink.com) have announced a first-of-its-kind strategic collaboration designed to advance the tattoo industry, creating safer, better products for customers [3]. Emulate and INTENZE will exclusively collaborate on innovative approaches for predicting human response to tattooing, expanding the functionality of Organs-on-Chips technology for chemical risk assessment applications. This initiative marks the first time that any group has applied Organ-Chips to systemically investigate the biological response associated with tattoo pigments, formulations or inks. In evaluating the human-relevant effects of tattoo ink, the collaboration will initially utilize Emulate's Skin-Chip, which recapitulates much of the complex biology represented in the human skin. In addition, Emulate will apply the company's other organ models, such as the Liver-Chip and the Kidney-Chip, to assess systemic exposure and possible toxicity risks of tattoo inks and other cosmetics and permanent cosmetic alterations. In partnering with

and support potential future regulatory requirements and the creation of relevant guidelines. INTENZE is the first tattoo ink manufacturer to publicly disclose the ingredients in each one of the tattoo inks it produces. This information allows customers and artists to know exactly what INTENZE inks are made with. INTENZE ink is also 100% vegan, containing zero animal products, and absolutely never tests on animals.

License agreement: CASI & Juventus

CASI Pharmaceuticals (MD, USA; www.casipharmaceuticals.com) has signed a license agreement for exclusive worldwide license and commercialization rights to an autologous anti-CD19 T-cell therapy product (CNCT19) from Juventas Cell Therapy (China; www.juventas.cn/en/index.html) [4]. Juventas will continue to develop CNCT19 with CASI's participation on the program's steering committee. CASI will be responsible for payment of certain future development milestones and sales royalties. In connection with the license, CASI Pharmaceuticals will invest US$11.6 (RMB 80) million in Juventas through a wholly owned Chinese subsidiary in lieu of the upfront payment for the license.

Manufacturing agreement: Gamida Cell & Lonza

Gamida Cell (Israel; www.gamida-cell.com) and Lonza (Switzerland; www.lonza.com) have entered into a strategic manufacturing agreement [5]. The agreement provides for the future commercial production after potential US FDA approval of omidubicel, Gamida Cell's investigational advanced cell therapy currently in clinical development designed to enhance the life-saving benefits of bone marrow HSC transplant. An international, randomized Phase III study of omidubicel in patients with hematologic malignancies is currently ongoing, and omidubicel has not yet been approved for marketing in the USA or any other jurisdiction. This agreement follows a successful multiyear clinical manufacturing relationship and provides Gamida Cell with a path to

Cell also has the option of expanding further into Lonza's global cell and gene therapy manufacturing network.

Partnership agreement: Mesoblast & JCR Pharmaceuticals

Mesoblast Limited (Australia; www.mesoblast.com) has expanded its partnership with JCR Pharmaceuticals (Japan; www.jcrpharm.co.jp/en/site/en/) in Japan to the use of mesenchymal stem cells (MSCs) for the treatment of newborns who lack sufficient blood supply and oxygen to the brain, a condition termed neonatal hypoxic ischemic encephalopathy (HIE) [6]. HIE occurs in 2.5 per 1000 live births and can cause seizures, delayed development of motor skills and cognitive function, and cerebral palsy. In preclinical studies, MSCs have been shown to have a significant positive effect on neurobehavioral outcome following HIE injury.

Partnership agreement: Tessa & China-Singapore Guangzhou Knowledge City

Tessa Therapeutics (Singapore; www.tessatherapeutics.com) will establish a joint venture with China-Singapore Guangzhou Knowledge City (CSGKC; China; www.ssgkc.com) [7]. The joint venture will be the sole licensee of Tessa's cell therapies for research, clinical development and commercialization in China. Tessa and CSGKC will invest a combined total of US$120 million in the joint venture – CSGKC will contribute US$80 million and Tessa will provide US$40 million – in two stages. In the first stage, CSGKC will contribute US$40 million for 13% stake in the joint venture while Tessa will contribute US$20 million and its technology license rights for China. Tessa will hold the remaining 87% stake in the joint venture.

Clinical trials

Mesenchymal stromal/stem cells (MSC)

This multicenter, open-label proof-of-concept Phase IIa study was designed to evaluate the safety and efficacy of ALLOB administered in addition to the standard of care procedure in which an interbody cage with bioceramic granules is implanted into the spine to achieve fusion of the lumbar vertebrae (https://clinicaltrials.gov; ID: NCT02328287). The primary end points of the study assessed at 12-month included radiological assessments to evaluate fusion (continuous bone bridges) and clinical assessments to evaluate improvement in patients' functional disability. The secondary end points included the assessment of intervertebral mobility (absence of motion at the treated lumbar level), back and leg pain reduction, as well as safety and tolerability. The study evaluated 30 patients treated with ALLOB in combination with standard of care procedure. Radiological data collected from CT scans over a 12-month period showed successful fusion ($p < 0.001$) of the lumbar vertebrae in 22 out of 30 patients (73.3%) while the remaining 8 patients showed evidence of bone formation. For the first 15 patients, who already reached the 24-month follow-up time point, 13 out of 15 patients (86.7%) showed successful fusion. Furthermore, treatment with ALLOB resulted in a clear and statistically significant clinical improvement from the pretreatment baseline in functional disability, with a mean score improvement of 63.0% ($p < 0.001$) on the Oswestry Disability Index. In addition, radiological data collected from dynamic x-rays at 12 months demonstrated that treatment with ALLOB resulted in the immobilization of the treated intervertebral segment in all patients. Finally, treatment with ALLOB resulted in a strong reduction in back and leg pain of 67.0 and 75.0%, respectively. The results from the study demonstrated that treatment with ALLOB was generally well tolerated. As previously described in the literature covering clinical studies with allogeneic mesenchymal stromal/stem cells (MSCs) or their derivatives, pre-existing or treatment-emergent antibodies have been detected in 64.5% of patients; however, no clinical consequences were observed.

announced results from the completed Phase I of the ZUMA-3 study evaluating KTE-X19, an investigational CD19 chimeric antigen receptor T (CAR T) cell therapy [9]. KTE-X19 has the same construct as axicabtagene ciloleucel; however, the manufacturing process for KTE-X19 differs from that of axicabtagene ciloleucel and includes the enrichment of lymphocytes. Lymphocyte enrichment is necessary in certain B-cell malignancies for which KTE-X19 in under investigation. KTE-X19 is currently in Phase I/II trials in acute lymphoblastic leukemia (ALL), mantle cell lymphoma and chronic lymphocytic leukemia. ZUMA-3 is a single-arm Phase I/II study in adult patients with relapsed or refractory ALL. The results provide guidance on dosing and safety management for KTE-X19 to inform the ongoing Phase II study. By the end of Phase I, 45 patients received KTE-X19 at one of three different doses levels (2 × 10 cells/kg [n = 6], 1 × 10 cells/kg [n = 23] or 0.5 × 10 cells/kg [n = 16]). Patients enrolled in this study were primary refractory or relapsed/refractory after at least two prior lines of therapy. Of 41 patients who were evaluable for efficacy after a minimum 2 months of follow-up (median follow-up of 16 months), 68% achieved complete response (CR) or CR with incomplete hematological recovery (CRi) and 100% of responders had undetectable minimal residual disease. Of the 23 patients treated with the dose level that will be used in the ongoing Phase II study (1 × 10 cells/kg), 19 were evaluable for efficacy. At the time of data cutoff (median duration of remission = 12.9 months), 16 (84%) patients achieved CR or CRi and 12 patients (75%) were in ongoing response. No dose-limiting toxicities were identified. Grade ≥3 cytokine release syndrome (CRS) events and neurologic events occurred in 29 and 38% of all patients, respectively. As previously reported, two patients experienced KTE-X19-related Grade 5 adverse events (AEs) during the study; one developed stroke in the context of CRS and neurologic events, and one experienced multi-organ failure secondary to CRS. Among patients receiving 1 × 10 cell/kg (n = 23), 26% experienced Grade ≥3 CRS and 43% experienced Grade ≥3 neurologic events. A revised AE

in cohort 2). Of those patients, two (22%) had Grade 3 CRS and one (11%) had Grade 3 neurologic events. There were no Grade 4/5 events.

Other

Enlivex

Enlivex (Israel; www.enlivex.com) has provided a clinical update on the positive safety profile of its Off-the-Shelf cell therapy, Allocetra™, in the first three severe sepsis patients, as part of its ongoing Phase Ib clinical trial (https://clinicaltrials.gov; ID: NCT03925857) [10]. This is the first infusion of Off-the-Shelf Allocetra in human subjects. Enlivex has developed Allocetra as a second-generation cell therapy to the matched donor Allocetra product, which has demonstrated a robust safety and clinical efficacy profile in a Phase IIa clinical trial for the prevention of graft versus host disease (GvHD) in patients following bone-marrow transplantation. Enlivex designed Allocetra to eliminate the need to find matched donors as the source of the therapeutic cells. This will allow Enlivex to manufacture therapeutic product inventory that could be used, post regulatory approval, for additional clinical indications. The first such indication Enlivex is currently targeting is the prevention of cytokine storms and organ dysfunction associated with sepsis. The three patients in the Phase Ib clinical trial of off-the-shelf Allocetra had severe sepsis at the time of Allocetra infusion. All three patients tolerated the infusion without serious AEs. All three patients demonstrated swift clinical improvement after administration of both the standard-of-care and Allocetra and were released from the hospital after the condition of severe sepsis has been eliminated. Following the results of the first three patients, Enlivex obtained regulatory approval for continued recruitment of patients into the Phase Ib clinical trial.

Follica

achieved a visible and statistically significant improvement in nonvellus (visible) hair count after 3 months of treatment, compared with baseline. Additionally, blinded head-to-head bench testing of the proprietary Follica device has shown significant therapeutic advantages in scalp treatment versus commercially available skin disruption devices. A pivotal study is expected to initiate at the end of 2019 subject to continued safety and efficacy in the optimization study. Follica's platform is designed to induce an 'embryonic window' in adult skin via a proprietary form of microabrasion that initiates hair follicle neogenesis, the formation of new hair follicles from epithelial (skin) stem cells. This process of hair follicle neogenesis is enhanced through the application of a topical compound as part of the treatment regimen. In addition to the ongoing safety and optimization study, Follica has proof-of-concept data from prior clinical studies using prototype devices with different treatment parameters and therapeutic compounds.

Minovia

Minovia Therapeutics (Israel; http://minovia.com) has announced dosing of the first patient in a Phase I/II clinical trial of the company's Mitochondrial Augmentation Therapy for the treatment of Pearson syndrome (https://clinicaltrials.gov; ID: NCT03384420) [12]. The Pearson syndrome trial is a Phase I/II, open label, single dose clinical study to evaluate the safety and therapeutic effects of transplantation of MNV-BM-BLD, Minovia's autologous $CD34^+$ cells enriched with blood-derived mitochondria, in pediatric patients. The trial will enroll a total of seven patients by invitation, and the primary outcome will be safety as determined by the number of participants with treatment-related AEs at 1 year, as well as improvement in quality of life as measured by the The International Paediatric Mitochondrial Disease Scale (IPMDS) questionnaire. Other outcomes measured at 1 year will include cognitive status, changes in brain MRI, changes in physical activity and muscle function, changes in weight and changes in peripheral blood lactate levels.

mitochondria manufactured by Minovia's proprietary Mitochondrial Augmentation Therapy platform will be transplanted via a single dose into pediatric patients with Pearson syndrome to increase the levels of normal mitochondrial DNA.

Pearson syndrome is caused by a deletion in the mitochondrial DNA and affects approximately 100 children globally. These deletions lead to poor energy production by the cells in the body. Pearson syndrome affects many parts of the body but especially the bone marrow and the pancreas. Pearson syndrome affects the HSCs in the bone marrow that produce red blood cells, white blood cells and platelets. Pearson syndrome also affects the pancreas, which can cause frequent diarrhea and stomach pain, trouble gaining weight and diabetes. Some children with Pearson syndrome may also have problems with liver, kidney, heart, eye, ear and/or brain function. Many children with Pearson syndrome die during infancy. Some children may survive into later childhood but may go on to develop Kearns–Sayre syndrome, a neuromuscular disorder defined by the triad of onset before age of 20 years, pigmentary retinopathy (a 'salt-and-pepper' pigmentation in the retina that can affect vision, but often leaves it intact) and progressive external ophthalmoplegia [13]. In addition, affected individuals have at least one of the following: cardiac conduction block, cerebrospinal fluid protein concentration greater than 100 mg/dl or cerebellar ataxia.

Regulations, approvals, acquisitions...

Regulations

US FDA

The FDA is giving a nudge to industry on stem cells with a new rapid-response program to help regenerative medicine makers to get on the right side of the law [14]. The Tissue Reference Group's Rapid Inquiry Program promises to answer sponsors' questions

framework for stem cells and other modern therapies in November 2017 but promised to give sponsors and makers 36 months of 'enforcement discretion' to come into compliance.

Green light

Allogene

Allogene Therapeutics (CA, USA; www.allogene.com), a clinical-stage biotechnology company pioneering the development of allogeneic CAR T (AlloCAR T™) therapies for cancer, has announced that the FDA has cleared its investigational new drug (IND) application for ALLO-715 in patients with relapsed/refractory multiple myeloma [15]. The Phase I portion of the UNIVERSAL study, which will include ALLO-647 as part of the lymphodepletion regimen, is expected to be initiated in the second half of 2019. ALLO-715, an AlloCAR T therapy targeting B-cell maturation antigen (BCMA), is a potential novel treatment for multiple myeloma and other BCMA-positive malignancies. ALLO-715 utilizes the TALEN® gene-editing technology pioneered and owned by Cellectis. Allogene has an exclusive license to the Cellectis technology for allogeneic products directed at the BCMA target. Allogene holds the global development and commercial rights for this investigational candidate.

AlloVir

AlloVir, formerly ViraCyte (TX, USA; www.allovir.com) has received regenerative medicine advanced therapy (RMAT) designation from the FDA for Viralym-M (ALVR105), its lead allogeneic, off-the-shelf, multivirus-specific T-cell therapy, for the treatment of hemorrhagic cystitis caused by BK virus in adults and children following allogeneic hematopoietic stem cell (HSC) transplantation [16]. Following positive Phase II clinical

Commission has granted conditional marketing authorization for ZYNTEGLO™ (autologous CD34$^+$ cells encoding β-globin gene), a gene therapy for patients 12 years and older with transfusion-dependent β-thalassemia who do not have a β/β genotype, for whom HSC transplantation is appropriate but a human leukocyte antigen-matched related HSC donor is not available [18]. A patient's HSCs are removed from the body through apheresis. These HSCs are taken to a lab where a lentiviral vector is used to insert the β-globin gene into the patient's HSCs. Before their modified HSCs are returned through infusion, a patient receives chemotherapy to prepare their bone marrow for the modified HSCs that now carry the β-globin gene. Once a patient has the β-globin gene he has the potential to produce hemoglobin A (HbA), which is gene therapy-derived hemoglobin, at levels that eliminate or significantly reduce the need for transfusions. Upon engraftment and achievement of transfusion independence, effects of ZYNTEGLO are expected to be lifelong. The conditional marketing authorization is valid in all 28 member states of the EU as well as Iceland, Liechtenstein and Norway. bluebird bio sets a price for ZYNTEGLO at US$1.78 (€1.58) million over 5 years. The company proposed an installment plan, with US$355,000 (€315,000) paid up front and four additional annual payments due only if the treatment continues to be effective. bluebird bio will continue the country-by-country reimbursement process to help ensure access to ZYNTEGLO for appropriate patients. ZYNTEGLO was reviewed as part of the EMA's Priority Medicines and Adaptive Pathways programs, which support medicines that may offer a major therapeutic advantage over existing treatments, or benefit patients without treatment options. The Priority Medicines and Adaptive Pathway programs allowed for early and enhanced dialog and accelerated assessment of ZYNTEGLO, which was completed on the shortest timetable for an advanced therapy medicinal product by the EMA to date.

CARsgen

Administration in China 4 months ago and is the subject of an ongoing Phase I clinical trial (https://clinicaltrials.gov; ID: NCT03915184).

Celgene & Acceleron

Celgene Corporation (NJ, USA; www.celgene.com) and Acceleron Pharma (MA, USA; www.acceleronpharma.com) have announced that the FDA has accepted Celgene's Biologics License Application (BLA) for luspatercept, an investigational erythroid maturation agent, for the treatment of adult patients with very low- to intermediate-risk myelodysplastic syndromes-associated anemia who have ring sideroblasts and require red blood cell transfusions, and for the treatment of adult patients with beta-thalassemia-associated anemia who require RBC transfusions [20]. The FDA has granted Priority Review to this BLA for the evaluation of the beta-thalassemia indication and set a Prescription Drug User Fee Act (PDUFA), or target action, date of December 4, 2019. The FDA has also set a PDUFA date of April 4, 2020 for the evaluation of the myelodysplastic syndrome indication. Acceleron and Celgene are jointly developing luspatercept as part of a global collaboration.

Enzyvant

Enzyvant (NC, USA; https://enzyvant.com), a wholly owned subsidiary of Roivant Sciences (Switzerland; https://roivant.com), has announced that the FDA has accepted for filing its BLA for RVT-802, a novel investigational tissue-based regenerative therapy designed to treat pediatric congenital athymia, and granted Priority Review [21]. Congenital athymia is a rare and deadly condition associated with complete DiGeorge Anomaly, CHARGE syndrome and FOXN1 deficiency. At this time, the FDA is not planning to hold an Advisory Committee meeting to discuss the application, and Enzyvant anticipates a regulatory decision in December 2019. Children with congenital athymia are born without a thymus, resulting in a severe immunodeficiency due to the inability to produce

therapies for this condition. Derived from infant thymus tissue, RVT-802 is processed and cultured prior to implantation into a patient's quadricep muscle. The patient's bone marrow stem cells migrate to the implanted tissue product, where they are trained to become naive, immunocompetent T cells. With the renewed ability to generate T cells, immune system function can be restored. RVT-802 has been granted Breakthrough Therapy, RMAT, Rare Pediatric Disease and Orphan Drug designations by the FDA.

Mesoblast

Mesoblast (Australia; www.mesoblast.com) has announced that the FDA has granted the company's product candidate, rexlemestrocel-L (Revascor), Orphan Drug Designation for prevention of postimplantation mucosal bleeding in end-stage chronic heart failure patients who require a left ventricular assist device (LVAD) [22]. Revascor consists of 150 million allogeneic mesenchymal precursor cells and is being developed for injection into heart muscle of patients with moderate-advanced or end-stage chronic heart failure. In a 30-patient placebo-controlled pilot trial in end-stage heart failure patients with LVADs, conducted by the NIH, a single intramyocardial dose of Revascor resulted in a 70% reduction in gastrointestinal bleeding and associated hospitalizations. These results supported the RMAT designation granted in December 2017 by the FDA for use of Revascor in LVAD patients.

Orgenesis

Orgenesis (Israel; www.orgenesis.com) has announced that the FDA has granted Orphan Drug designation for its autologous insulin-producing cells as a cell replacement therapy for the treatment of severe hypoglycemia-prone diabetes resulting from total pancreatectomy due to chronic pancreatitis [23]. The company's patented transdifferentiation (or cell reprogramming) process involves the conversion of one adult tissue or cell into another type of cell, with its distinct phenotype and function.

expansion capabilities. At the appropriate time, the cells may be converted into functional glucose-regulated AIP cells through the company's proprietary transdifferentiation process and returned to the patient's liver via a transfusion. The goal is to provide a 'practical cure' for various types of insulin-dependent diabetes, thus hopefully providing long-term insulin independence without the need for concomitant immunosuppressive therapy.

Torque

Torque (MA, USA; www.torquetx.com), a clinical-stage immunooncology company developing Deep-Primed™ T-cell therapeutics to direct immune power deep within the tumor microenvironment, has announced that the FDA granted Fast Track designation for Torque's first Deep-Primed™ T-cell immunotherapy program, TRQ-1501 (Deep IL-15 Primed T cells) [24]. The Fast Track designation is for the treatment of relapsed or refractory solid tumors and lymphomas that express any of five tumor-associated antigens (PRAME, WT-1, SSX2, Survivin and NY-ESO-1). Torque is currently conducting a Phase I/II clinical trial of TRQ-1501 for this indication.

Triumvira

Triumvira Immunologics (TX, USA; www.triumvira.com) has announced that both the FDA and Health Canada have cleared Triumvira's IND and Clinical Trial Applications for its novel T-cell therapy product TAC01-CD19 in patients with CD19-postive B-cell malignancies [25]. The Phase I/II study (TACTIC-19) is expected to be initiated in the third quarter of 2019.

Acquisitions

Kiadis & CytoSen

to revolutionize hematopoietic stem cell transplantation (HSCT) and create a pipeline with novel cancer treatments. Kiadis now has a complementary development pipeline focused on improving outcomes for patients HSCT with a T-cell therapy (ATIR101; in EU registration and a global Phase III clinical trial) and a natural killer cell therapy (CSTD002; expected to enter the clinic in the USA in 2020).

Capital market & finances

GPB Scientific

GPB Scientific (CA, USA; www.gpbscientific.com) has announced that the NIH completed its review or its achievement of Phase I milestones and authorized Phase II funding under a US$2.2 million NIH Small Business Technology Transfer Award [27]. The award by the National Cancer Institute of the National Institutes of Health supports work by GPB Scientific, in collaboration with the University of Maryland School of Medicine (MD, USA; www.medschool.umaryland.edu) and Princeton University (NJ, USA; www.princeton.edu), to scale up GPB Scientific's microfluidic cell separation technology. GPB Scientific's innovation displaces current centrifuge-based systems for selecting cells, such as isolating a patient's own white blood cells from red cells and platelets to manufacture ground-breaking CAR-T cancer therapies. In Phase I, GPB Scientific demonstrated the ability to process apheresis blood material and obtain >95% recovery of white cells, >99% removal of red cells and >95% removal of platelets, with throughput of 300–500 ml/h. This is a gentle, reagent-free, closed system that can enable automation of cell manufacturing for T-, stem- and other cell therapies.

InGeneron

InGeneron (TX, USA; www.ingeneron.com) has announced the extension of its Series D financing by up to US$23 million, totaling up to US$43 million to be invested in the

study in rotator cuff tendinopathy, a degenerative and often chronic condition found in a person's shoulder, as well as other clinical programs in its autologous point-of-care cell therapy portfolio. Last month, the company announced the enrollment of the first patients in its rotator cuff tendinopathy pivotal trial.

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