Genenta Science宣布完成新一轮1320万欧元融资 基于基因疗法治疗癌症的两项临床试验进展顺利

药时代　昨天

- **Genenta Science宣布完成新一轮1320万欧元融资**
- **成立至今总计募得超过3000万欧元融资**
- **基于基因疗法治疗癌症的两项临床试验进展顺利**

2019年9月11日，米兰（意大利）/纽约——总部位于欧洲的生物科技公司Genenta Science今天宣布：公司已经完成了第三次融资，本轮融资金额为1320万欧元（约1亿人民币）。至此，从Genenta成立至今已获得三轮融资，共募集3020万欧元。

目前公司专注于在研产品——骨髓干细胞基因疗法Temferon™的两个癌症适应症的 Phase I/II 临床试验进展顺利，其中一个用于治疗血液肿瘤——早期复发的多发性骨髓瘤，另一个则针对实体瘤— —新诊断的多形性胶质母细胞瘤。

本轮融资由乾瞻投资（QZ）和Fidim共同领投。

乾瞻投资是一家位于上海的投资公司，其业务包括期货、证券和一级市场的投资。目前，乾瞻在管理一支50亿人民币（约 7.2 亿美元）的基金，专注于投资中国、美国和欧洲的生物技术和IT技术初创公司。乾瞻是腾讯音乐（NYSE: TME）的早期投资人之一。乾瞻在制药方面的投资企业包括： 武汉海特生物 (300683.SZ)，Capella Therapeutics (圣地亚哥，加州)和索元生物医药（圣地亚哥，加 州）等。

Fidim是Rovati家族的控股公司。该家族是Rottapharm（一家制药公司，后其商务业务被Meda以22亿欧元收购）的前持有人。Fidim保留了Rottapharm的研发业务，以 Rottapharm Biotech 的名称继续运营。2016年，Meda被Mylan（NASDAQ: MYL）收购。

乾瞻投资和Fidim都将作为观察员进入Genenta公司董事会。其中乾瞻投资由负责公司生物科技

风险投资的医学博士刘璟作为代表，Fidim由Rottapharm Biotech首席运营官和首席医学官医学博士Lucio Rovati出任代表。

Bormioli家族和Fumagalli家族和此前两轮的投资人也参与了本轮融资。Bornioli家族是Advance Accelerator Applications的早期投资人，Advance Accelerator Applications 此前是纳斯达克上市生物科技公司，后被诺华（NYSE: NVS）以39亿美元收购。Fumagalli家族以前是Candy公司的持有人，Candy被中国的海尔集团以5.47亿美元收购。公司的第一轮融资由Mediobanca(BIT: MB)作为财务顾问。伦敦证券交易所集团旗下ELITE公司推动了本轮融资。

“得益于Genenta在基因治疗产品临床前开发和临床开发富有经验的团队，公司在本轮融资前申请、获得了临床研究批件，开始生产，并启动了2项临床试验。” Genenta董事长兼CEO、公司联合创始人Pierluigi Paracchi表示：“ Genenta公司团队由基因治疗领域富有声望的科学家和临床医生组成 ，可谓在一个天时地利人和的环境中成长起来 。从一开始，我们就决定利用SR-TIGET （ San Raffaele Telethon Institute for Gene Therapy ）在临床前和临床开发基因治疗用于罕见病，并将产品带到市场上成功经验，自己将Temferon带到First in Human。因为对整个项目都全盘控制，我们能够更好的朝着我们的目标，在许可产品、公司并购或者IPO之前创造最大的价值。”

“Genenta正在开发一种创新的首创技术平台，通过用基因改造过的骨髓造血干细胞 ，将免疫刺激剂干扰素靶向送到肿瘤微环境。从公司创立以来，Genenta能够高效地应对这项创新技术平台开发过程中的挑战 ，并利用SR-TIGET （San Raffaele Telethon Institute for Gene Therapy ）在基因治疗开发方面的成功经验， 将这一技术快速推进到临床试验。SR-TIGET是全球基因治疗用于罕见病的领先者 ，在过去的10年间已经治疗了100多个患者。”SR-TIGET负责人和Genenta联合创始人Luidi Naldini教授介绍。

“Genenta在研产品目前靶向2个肿瘤适应症，一个针对实体瘤，另一个针对血液肿瘤：多形性胶质母细胞瘤和多发性骨髓瘤。” Genenta首席医学官Carlo Russo（医学）博士解释。“临床前的分析结果显示： Temferon针对 这两 种癌症有非常好的疗效， 并在人体试验中获益大于风险 。临床试验起始的主要目标是Temferon对于患者的临床安全性， 此后是剂量递增的安全性和有效性。有效性将会用生物标志物来衡量，包括肿瘤微环境免疫激活的生物标识和疾病进展。”

关于Genenta Science

Genenta (www.genenta.com) 开发了一种创新基因疗法，通过体外基因转染自体骨髓干/组细胞， 将免疫调节分子通过肿瘤浸润的单核细胞/巨噬细胞（表达Tie2的单核细胞-TEMs）靶向递送到肿瘤微环境的基因疗法。目前专有在研产品是 Temferon™。

在TEM中靶向表达免疫调节分子是通过转录和转录后的mi-RNA介导的调节实现。因为这些机制，TEMs 能够在肿瘤微环境中表达免疫调节分子干扰素-α。

TEMs具有促进血管新生的作用，因此会被肿瘤募集到肿瘤微环境，促进肿瘤生长。通过导入免疫调节分子基因，TEMs成为了靶向肿瘤微环境递送免疫调节分子的工具细胞。在临床前肿瘤模型中，被靶向递送到肿瘤免疫微环境内的干扰素-α显示了直接的抗肿瘤作用（抑制血管新生，促进凋亡）和间接的抗肿瘤（提高免疫应答）作用。

和Car-T疗法不同的是，Temferon™不仅能够治疗血液肿瘤，还能够治疗实体瘤。并且 Temferon™ 的免疫调节功能可能会激活多种肿瘤抗原，免疫反应的持续时间更长。

因此，Temferon™能够通过重编程肿瘤微环境，打破肿瘤微环境内的免疫耐受。

Genenta Temferon™ 获得了两个适应症的Phase I/II临床试验许可，其中一个适应症是一线治疗后早期复发的多发性骨髓瘤，另外一个适应症是新诊断的多形性胶质母细胞瘤。Genenta的总部在意大利米兰，在美国纽约的 Alexandria Center's LaunchLabs 有办公室。Genenta是Assobiotec, Italia StartUp, 和伦敦证券交易所旗下ELITE的成员。

Co-founders: Pierluigi Paracchi, Ospedale San Raffaele (OSR), prof. Luigi Naldini (Director SRTIGET, San Raffaele Telethon Institute for Gene Therapy), and Bernhard Gentner (Hematologist and Physician-Scientist at OSR and SR-TIGET).

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Genenta Science announces 13,2 Million in a New Round of Financing, hits a total

above 30 Million since inception. Two clinical trials ongoing.

September 11, 2019

MILANO (Italy) / NEW YORK (NY, USA) -- Genenta Science, a clinical-stage biotechnology company pioneering the development of hematopoietic stem cell gene therapies for cancer (Temferon™), today announced the closing of its third Round adding €13,2M in a total of €30,2M since incorporation. Two Phase I/II clinical trials are currently ongoing in two different indications, early relapse Multiple Myeloma - a hematologic disorder, and newly diagnosed Glioblastoma Multiforme - a solid tumor.

The Round was led by Qianzhan Investment Management (QZ) and Fidim. QZ is a Chinese private investment company based in Shanghai operating in futures trading, stock trading, and private equity investments. Currently, QZ has allocated $720M to private equity and venture capital in tech and life sciences, investing in China, US and Europe. QZ was one of the first and is currently an investor in Tencent Music (NYSE: TME). QZ is also an investor in Wuhan Hiteck (300683.SZ), Capella Therapeutics (San Diego, CA), Denovo Biopharma (San Diego, CA), among others. Fidim is the holding company of the Rovati family, the former owner of Rottapharm, a pharma company whose commercial activity was acquired by Meda for shares and equity value of €2.2B. Fidim retained the R&D operations as Rottapharm Biotech. In 2016, Meda was acquired by Mylan (NASDAQ: MYL). Both QZ and Fidim will be Observers in Genenta's Board of Directors. QZ will be represented by Jing "Akira" Liu, MD, in charge of QZ's biotech venture capital investments and Fidim will be represented by Lucio Rovati, MD, the CEO and CSO of Rottapharm Biotech.

Bormioli and Fumagalli families, and part of the Investors of the previous two Rounds (including "Club degli Investitori", a business angel network) were among the other investors of the current Round. Bormioli was an early investor in Advanced Accelerator Applications, a biotech company listed on NASDAQ and then acquired by Novartis (NYSE: NVS) for $3.9B. Fumagalli is the former owner of Candy, a company acquired for $547M by the Chinese electronics giant Haier Group. The Investors of the first Round were supported by Mediobanca (BIT: MB) as advisor. ELITE, the international platform of the London Stock Exchange Group, promoted the current Round of the capital raise through its private placement platform.

"Filing for regulatory approvals, product's manufacturing, and initiating two clinical trials prior to the current Round is a remarkable achievement in large part due to an experienced team in

developing gene therapy products", said Pierluigi Paracchi, Chairman & CEO and Co-founder. "Genenta is growing in a favorable environment that puts together great scientists and qualified physicians. From the beginning, we decided to leverage on SR-TIGET previous successful experience in bringing gene therapies for rare diseases to the clinic and to the market, and to take all the steps ourselves up to First in Human. Retaining full control of the project, we could best steer towards our goal and create the greatest amount of value possible ahead of licensing out, M&A or IPO".

"Genenta is developing a highly innovative first-of-its-kind platform of targeted delivery of immune activating interferon to the tumor microenvironment by genetically engineered hematopoietic cells. Since its launch, Genenta was able to effectively meet the challenges raised by this new approach and quickly reach the stage of first clinical testing also by leveraging on the successful experience of the San Raffaele Telethon Institute for Gene Therapy (SR-TIGET), which has pioneered several novel gene therapies for rare diseases and has treated >100 patients in the past decade", said prof. Luigi Naldini, SR-TIGET Director and Genenta's Cofounder.

"Genenta has two initial tumor targets, one solid and one hematopoietic: Glioblastoma Multiforme and Multiple Myeloma", Carlo Russo, MD Genenta's CMO added. "The results from the preclinical analysis showed that the drug product's activity in those tumors could have the best therapeutic index and risk-benefit profile for First in Human testing. The initial major goal is to demonstrate the safety of our therapeutic approach once deployed in the clinic, following by the safety and efficacy response to dose-escalating. Measurements of efficacy will include biological markers, evidence of induced immune activation within the tumor microenvironment and ultimately in disease progression".

About Genenta Science

Genenta (www.genenta.com) develops an ex-vivo gene transfer strategy into autologous hematopoietic stem/progenitor cells (HSPCs) to delivery immunomodulatory molecules directly via tumor-infiltrating monocytes/macrophages (Tie2 Expressing Monocytes - TEMs). Genenta's proprietary product is Temferon™. The targeted expression of the immunomodulatory molecule in TEMs is achieved combining a transcriptional and post-transcriptional microRNA-mediated control. Thanks to these mechanisms, TEMs become capable to express the immunomodulatory molecule (Interferon-alpha, "IFN-α") in the tumor microenvironment. TEMs are endowed

with a pro-angiogenic activity and are spontaneously and actively recruited by developing tumors to sustain their growth. Thanks to the immune-gene transfer, TEMs become the tool for the local delivery of the immunomodulatory molecule. In the preclinical models, the local IFN-α release triggered both a direct (anti-angiogenic, pro-apopototic) and an indirect anti-tumor effect (immune response). In contrast to antigen-restricted Chimeric Antigen Receptor T cells (CAR-T), Temferon™ may reach not only hematologic disorders but more importantly, also solid tumors. In addition, its immune-modulatory functions may trigger a long-lasting immune response towards multiple tumor antigens. As a result, Temferon™ should be able to break the tumor immune-tolerance by reprogramming the tumor immune microenvironment. Genenta obtained the regulatory approvals for two Phase I/II clinical trials in early relapse Multiple Myeloma patients after front line therapy and newly diagnosed Glioblastoma Multiforme patients. Genenta's headquarter is in Milano (Italy) and Genenta has an office in Alexandria Center's LaunchLabs, New York (NY, USA). The Company is part of Assobiotec, Italia StartUp, and ELITE (London Stock Exchange Group). Co-founders: Pierluigi Paracchi, Ospedale San Raffaele (OSR), prof. Luigi Naldini (Director SR-TIGET, San Raffaele Telethon Institute for Gene Therapy), and Bernhard Gentner (Hematologist and Physician-Scientist at OSR and SR-TIGET).

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