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₩ 东陽光药

廣東東陽光藥業股份有限公司 SUNSHINE LAKE PHARMA CO., LTD.

(一間於中華人民共和國註冊成立的有限公司)

YiChang HEC ChangJiang Pharmaceutical Co., Ltd. 宜昌東陽光長江藥業股份有限公司

(在中華人民共和國註冊成立之股份有限公司) (股份代號:01558)

廣東東陽光藥業股份有限公司、宜昌東陽光長江藥業股份有限公司 與瀋陽三生製藥有限責任公司就商業化 苯磺酸克立福替尼達成授權許可協議



要約人的財務顧問



茲提述(i)廣東東陽光藥業股份有限公司(「**要約人**」)與宜昌東陽光長江藥業股份有限公司(「**本公司**」)於二零二四年五月十日聯合刊發的公告(「**聯合公告**」),內容有關合併;(ii)要約人與本公司就延遲寄發綜合文件於二零二四年六月七日聯合刊發的公告;及(iii)要約人與本公司就有關合併的月度更新於二零二四年七月五日、二零二四年八月五日、二零二四年九月四日及二零二四年十月四日及二零二四年十一月五日聯合刊發的公告。除非文義另有所指,本公告所用詞匯與聯合公告所界定者具有相同涵義。

本公告乃要約人及本公司根據收購守則規則8.1而發出。

要約人及本公司謹此向本公司股東提供隨附之新聞稿,內容有關要約人、本公司與瀋陽三生製藥有限責任公司(「瀋陽三生」)(一家位於中國瀋陽的生物製藥公司並為三生製藥(一家在香港聯合交易所主板上市的公司(股票代碼:1530))的附屬公司)簽署有關苯磺酸克立福替尼的授權許可協議。根據協議的條款,瀋陽三生獲授予苯磺酸克立福替尼在中國關於特定適應症的獨家商業化權益,而要約人的條款,要約人有望在授權許可協議的有效期內收取人民幣6千萬元的首付款,此外還將有望收取研發註冊及商業里程碑付款。研發註冊里程碑付款取決於是否在各到協議的研究階段及特定監管機構的批准。商業里程碑付款則取決於能否在各到協議的研究階段及特定監管機構的批准。商業里程碑付款則取決於能否在各主要市場達到協議的年銷售額。在苯磺酸克立福替尼在中國首次商業銷售克主营主意,要約人將在協議有效期內每月向瀋陽三生支付其該月在中國就苯磺酸克立福替尼銷售的淨回款到賬金額的約定百分比作為服務費。授權許可協議的有效期為簽署日起到首次商業銷售之日起至少十五年。授權許可協議乃本公司與要約人在2023年11月29日簽訂的藥品研發管線合作項目框架協議項下有關藥品商業化的落實措施。

警告:概不保證(1)要約人、本公司或瀋陽三生最終將成功開發、上市及/或商業化該產品,(2)要約人能否取得授權許可協議項下的有關里程碑付款及(3)授權許可協議對要約人及本公司盈利能力的影響。本公司股東及潛在投資者在買賣本公司股份時務請審慎行事。

前提條件及生效條件必須於合併協議生效前達成。因此,合併協議生效僅為一種可能性。此外,股東、本公司證券的投資者及潛在投資者應知悉,合併的實施須待聯合公告所載實施條件達成或獲豁免(如適用)後方可作實。要約人或本公司概不保證能達成任何或全部該等條件或前提條件,因此合併協議可能生效亦可能不會生效,或倘生效,亦不一定會實施或完成。因此,股東、本公司證券的投資者

及潛在投資者在買賣本公司證券時應謹慎行事。對將予採取的行動和合併所產生的影響有任何疑問的人士,應徵詢其股票經紀、銀行經理、律師或其他專業顧問的意見(包括徵詢稅務顧問有關注銷股份及實施合併的稅務後果的意見)。

美國的H股股東須知

合併將根據中國法律之規定以吸收合併方式實施,涉及交換兩間在中國註冊成立 之有限公司的證券及注銷一間於中國註冊成立之有限公司的證券。合併須遵守香 港披露規定,且有關披露規定有別於美國規定。本公司的公告中所載之財務資料 乃根據國際財務報告準則編製,因此未必可與美國公司或按美國公認會計準則編 製其財務報表之公司之財務數據進行比較。

由於要約人及本公司均位於美國以外的國家,且彼等各自部分或全部高級職員及董事可能是美國以外國家的居民,因此美國的H股股東可能難以強制執行其根據美國聯邦證券法的權利及所產生的任何申索。美國的H股股東可能無法在非美國法院就違反美國證券法起訴一間非美國公司或其高級職員或董事。此外,美國的H股股東可能難以迫使一間非美國公司及其聯屬人士服從美國法院的判決。

根據收購守則及美國證券交易法第14e-5(b)條,中金公司及其聯屬人士可繼續於聯交所擔任股份的獲豁免自營買賣商。此等購買可按現行價格於公開市場進行或按磋商價透過私人交易進行,惟任何該等購買或安排均須遵守適用法律(包括但不限於收購守則)並於美國境外進行。有關該等購買的任何資料將根據收購守則的規定呈報予證監會,並在證監會向公眾公開的情況下可於證監會網站http://www.sfc.hk及聯交所網站www.hkexnews.hk進行查閱。

承董事會命 廣東東陽光藥業股份有限公司 主席 張英俊 承董事會命 宜昌東陽光長江藥業股份有限公司 主席 唐新發

中國湖北 二零二四年十一月二十五日 於本聯合公告日期,要約人的董事為張英俊博士、李文佳博士、張寓帥先生、唐新發先生、朱英偉先生、東曉維女士、王蕾女士、李新天博士、馬大為博士、尹航博士及林愛梅博士。要約人的董事願就本聯合公告所載資料(與本公司或董事(以此身份)有關的資料除外)的準確性共同及個別承擔全部責任,並於作出一切合理查詢後確認,就彼等所深知,於本聯合公告中所表達意見(由本公司或董事以其身份所表達者除外)乃經審慎周詳考慮後作出,且本聯合公告並無遺漏任何其他事實,致使本聯合公告的任何陳述有所誤導。

於本聯合公告日期,董事會包括執行董事蔣均才先生、王丹津先生、李爽先生及陳浩先生;非執行董事唐新發先生;及獨立非執行董事唐建新先生、向凌女士及李學臣先生。董事願就本聯合公告所載資料(與要約人或其董事(以此身份)有關的數據除外)的準確性共同及個別承擔全部責任,並於作出一切合理查詢後確認,就彼等所深知,於本聯合公告中所表達意見(由要約人或其董事以其身份所表達者除外)乃經審慎周詳考慮後作出,且本聯合公告並無遺漏任何其他事實,致使本聯合公告的任何陳述有所誤導。

东阳光药与三生制药就苯磺酸克立福替尼开展合作 THE COOPERATION BETWEEN SUNSHINE LAKE PHARMA AND 3SBIO INC. IN RELATION TO CLIFUTINIB BESYLATE

2024年11月25日,广东东阳光药业股份有限公司(以下简称东阳光药)及其子公司宜昌东阳光长江药业股份有限公司(以下简称东阳光长江药业)与三生制药旗下沈阳三生制药有限责任公司(以下简称沈阳三生)就苯磺酸克立福替尼(以下简称克立福替尼)达成合作协议。

On 25 November 2024, Sunshine Lake Pharma Co., Ltd. (hereinafter referred to as Sunshine Lake Pharma) and its subsidiary, Yi Chang HEC Chang Jiang Pharmaceutical Co., Ltd. (hereinafter referred to as Yi Chang HEC), entered into a cooperation agreement with Shenyang Sunshine Pharmaceutical Co., Ltd. (hereinafter referred to as Shenyang Sunshine) under 3SBio Inc. in relation to Clifutinib besylate (hereinafter referred to as Clifutinib).

根据协议的条款,东阳光药将克立福替尼在中国大陆关于特定适应症的商业化权利独家许可给沈阳三生。东阳光药在协议有效期内有望收取人民币6,000万元首付款,此外还将有望收取研发注册及商业里程碑付款。研发注册里程碑付款取决于是否能达到协议的研究阶段及特定监管机构的批准。商业里程碑付款则取决于能否在各主要市场达到协议的年销售额。在克立福替尼在中国首次商业销售并回款后以及在协议有效期内,东阳光药将每月向沈阳三生支付其该月相关净回款到金额的约定百分比作为服务费。合作协议的有效期为签署日起到首次商业销售之日起至少十五年。同时,东阳光药将继续负责克立福替尼的研发、注册(包括作为上市许可持有人(MAH))和生产;沈阳三生将独家负责克立福替尼在中国大陆的商业化。

Pursuant to the terms of the agreement, Sunshine Lake Pharma exclusively licensed to Shenyang Sunshine the rights to commercialize Clifutinib in mainland China for specific indications. Sunshine Lake Pharma will receive an initial payment of RMB 60 million and payments for research and development (hereinafter referred to as R&D) and sales milestone over the term of the agreement. The development and registration milestone payments are contingent upon reaching defined research stages and obtaining certain regulatory approvals within a specific timeframe, among other defined circumstances. The commercial milestone payments are contingent upon reaching defined annual sales thresholds. Following the first commercial sale of Clifutinib in China and in each month during the term of the agreement, Sunshine Lake Pharma will pay an agreed percentage of the net sale proceeds the Offeror received in respect of the sale of Clifutinib in China in that month as service fee to Shenvang Sunshine. The agreement's term is from the date of signing of the agreement to at least fifteen years following the date of the first commercial sale. Meanwhile, Sunshine Lake Pharma will continue to be responsible for the R&D, registration (including as a marketing authorization holder (MAH)) and manufacturing of Clifutinib, and Shenyang Sunshine will be exclusively responsible for the commercialization of Clifutinib in mainland China.

克立福替尼是东阳光药自主研发的第二代高选择性FLT3口服小分子抑制剂,拟定适应症为FLT3-ITD突变的急性髓性白血病(AML)。相较于第一代药物,克立福替尼展现出更强的FLT3抑制活性,更低的脱靶风险与更优的安全性。

Clifutinib, the second-generation of a highly selective oral small molecule inhibitor for FLT3, is independently developed by Sunshine Lake Pharma with the proposed indication of acute myeloid leukemia (AML) with FLT3-ITD mutation. Compared with the first-generation drug, Clifutinib exhibits stronger FLT3 inhibitory activity, potential of lower off-target effect and better safety profile.

AML是中国最常见的白血病亚型,占所有白血病患者的一半以上。AML在30岁以下的人群中发病率比较低,之后随年龄逐渐升高,在70岁以上的老年人群中发病率最高,中位发病年龄68岁。AML进展快速,是死亡率最高的白血病亚型,由于起病隐匿、病情危重,使临床上对AML进行治疗面临较大挑战,亟需更好的创新药物以满足临床需求。

AML is the most common subtype of leukemia in China, accounting for more than half of all leukemia patients. The incidence of AML is relatively low in people under 30 years of age, and then gradually increases with age. It has the highest incidence in the elderly population over 70 years of age, with a median age of onset of 68. AML progresses rapidly, and is the subtype of leukemia with the highest mortality rate. Due to its insidious onset and critical condition, AML is challenging to treat in the clinical setting, which urges for better innovative drugs to meet the clinical needs.

克立福替尼单药治疗复发/难治AML目前正在国内进行III期临床,是国内首个进入III期临床的国产高选择性FLT3抑制剂,其联合化疗针对初治AML患者的Ib/II期临床也正在同步开展。早前I期结果显示,克立福替尼在AML患者表现出较高的CR/CRh率和良好的耐受性。

Clifutinib monotherapy for relapsed/refractory AML has entered Phase III clinical trial, which is the first highly selective FLT3 inhibitor developed domestically to enter Phase III clinical trial in China, and its Phase Ib/II clinical trial in combination with chemotherapy for naive AML patients is being carried out simultaneously. Early phase I results showed that Clifutinib exhibits high CR/CRh rate and good tolerability in AML patients.

东阳光药坚持创新和国际化战略,以开发未满足的临床需求药物为己任,在代谢、肿瘤、感染等治疗领域取得了一系列重要成就。目前,公司正在快速推进克立福替尼的III期临床试验,希望尽快为AML患者的治疗带来新的机遇。

Sunshine Lake Pharma, with its mission of developing drugs with unmet clinical needs, focuses on its innovation and internationalization and has made significant achievements in therapeutics areas such as metabolic disease, oncology and anti-infective. Currently, the company is fast-tracking the Phase III clinical trial of Clifutinib in the hope of bringing new treatment opportunities for AML patients as soon as possible.

东阳光药董事长张英俊博士表示:「很高兴与三生制药达成克立福替尼的商业化合作。东阳光药致力于在感染、慢病、肿瘤三大领域为患者带来更好的药物。苯磺酸克立福替尼作为国产药物首个进入III期临床的高选择性FLT3口服小分子抑制剂,早期临床已验证了突出的临床疗效和良好的安全性,展示了巨大的临床价值。三生制药作为中国领先的生物技术公司,具有高效的推广团队和强大的商业化能力,尤其在血液疾病领域,与苯磺酸克立福替尼的临床价值深度契合,我们期待双方充分发挥各自的优势,尽早推进上市和商业化,为国内AML患者带来新的治疗曙光。」

Dr. ZHANG Yingjun, the Chairman of Sunshine Lake Pharma, commented that, "We are very pleased to cooperate with 3SBio Inc. in the commercialization of Clifutinib. Sunshine Lake Pharma is committed to bringing better medicines to patients in the three major areas of anti- infective, chronic disease and oncology. Being the first highly selective oral small molecule inhibitor for FLT3 developed domestically to enter Phase III clinical trial, Clifutinib has been verified by early clinical trials for its outstanding clinical efficacy and favorable safety profile, demonstrating great clinical value. 3SBio Inc., as a leading biotechnology company in China with an efficient promotion team and strong commercialization capabilities, especially in the field of blood disorders, is highly compatible with the clinical value of Clifutinib besylate. We look forward to both parties fully utilizing their respective strengths to ensure a swift launch and commercialization, thereby bringing a new ray of hope for AML patients in China."

三生制药董事长兼首席执行官娄竞博士表示:「白血病是威胁人类健康的常见恶性肿瘤之一,其中急性髓系白血病为最常见类型。三生制药始终以未满足的临床需求为目标,致力于不断为患者带来更好的临床解决方案。东阳光药的克立福替尼作为第二代FLT3抑制剂,具有创新的作用机制,在前期的临床试验中也观察到了良好的疗效。我们期待该产品早日获批上市。三生制药与东阳光药将一起携手努力,共同为患者造福。」

Dr. LOU Jing, the Chairman and Chief Executive Officer of 3SBio Inc., commented that, "Leukemia is one of the most common malignancies threatening people's health, and acute myeloid leukemia is the most common type of it. With an unwavering emphasis on unmet clinical needs, 3SBio Inc. is committed to bringing better clinical solutions to patients on a continuous basis. Sunshine Lake Pharma's Clifutinib, a second-generation FLT3 inhibitor, has an innovative mechanism of action with good efficacy being observed in early clinical trials. We look forward to its early approval for launch in the market. 3SBio Inc. will collaborate with Sunshine Lake Pharma for the betterment of patients."

关于FLT3

FLT3是一种受体酪氨酸激酶,对造血干细胞的正常发育起着至关重要的作用,大约三分之一的AML患者携带FLT3突变。FLT3抑制剂通过干扰FLT3-ITD突变驱动的细胞无限增殖及抗凋亡机制,从而达到对AML有效治疗的目的。

About FLT3

Approximately one-third of AML patients carry mutation in FLT3, a receptor tyrosine kinase that plays a critical role in the normal development of hematopoietic stem cells. FLT3 inhibitors are effective in the treatment of AML by interfering with the unlimited cell proliferation and anti-apoptosis mechanisms driven by the FLT3-ITD mutation.

关于东阳光药

广东东阳光药业股份有限公司成立于2003年,是一家综合性制药公司,从事药物的研发、生产和商业化;东阳光药涵盖创新药,改良型新药、仿制药和生物类似药等,经过二十多年的积累,已建成行业领先的研发平台、符合国际标准的生产设施与覆盖全球的销售网络。公司战略性地聚焦感染、慢病及肿瘤等治疗领域,在全球拥有147款获批药物,超过100款在研药物,包括45款一类在研创新药,其中三款创新药递交上市申请及十款在研创新药物处于II期或III期临床试验。东阳光药的使命是为全球患者提供创新、优质及可负担的药物。东阳光药的愿景是专注于创新和国际化,凭藉优秀的商业化能力成为世界一流的制药企业。

About Sunshine Lake Pharma

Established in 2003, Sunshine Lake Pharma is a vertically integrated pharmaceutical company focused on the R&D, production, and commercialization of innovative drugs, and has a presence in the field modified new drugs, generic, and biosimilars. Since its founding, Sunshine Lake Pharma has built industry-leading R&D platforms, manufacturing facilities, and a global sales network. The company strategically targets infectious diseases, oncology, and chronic metabolic diseases, with 147 approved drugs in the world and more than 100 drugs in the pipeline, including 45 Class I innovative drug candidates among which three innovative drugs are under review for launching and ten innovative drug candidates in Phases II or III clinical trials. Sunshine Lake Pharma's mission is to provide innovative, high-quality and affordable medications to patients around the world and its vision is to become a world-class pharmaceutical company by focusing on innovation, internationalization and leveraging our excellent commercialization capabilities.

关于三生制药

三生制药是一家集研发、生产和销售为一体的生物制药领军企业,致力于以高品质的药品提高患者生存质量,为人类健康造福。目前,公司拥有100余项国家发明专利授权,40余种上市产品,覆盖肾科、肿瘤科、自身免疫性疾病、眼科及皮肤科等多种治疗领域。公司拥有抗体药物国家工程研究中心以及生物药和化药双平台的4大研发中心,共有28种在研产品,其中25种为国家新药,并拥有符合GMP标准的5大生产基地。未来,三生制药将继续秉持「珍爱生命、关注生存、创造生活」的理念,全力打造全球领先的中国生物制药企业。

About 3SBio Inc.

3SBio Inc. is a leading biopharmaceutical company integrating R&D, production and sales, with a focus on improving the life quality of patients with high quality medicines to benefit people's health. The company currently owns more than 100 national invention patents and has launched more than 40 products on the market, covering several treatment fields including, among others, nephrology, oncology, autoimmune, ophthalmology and dermatology. The company has a National Engineering Research Center of Antibody Medicine and four R&D bases with dual platforms for biopharmaceutical and chemical medicines. Amongst the 28 product candidates within the company's active pipeline, 25 are being developed as innovative drugs in China. The company also owns five production bases that are GMP-compliant. In the future, 3SBio Inc. will continue to uphold the vision of "Care for Life, Cherish Life, Create Life" to build a world-leading biopharmaceutical company in China.