KBP-7072 obtained QIDP and Fast Track Designations

(Jinan, China, and Princeton, NJ) KBP BioSciences, a clinical stage biopharma company announced today that the U.S. Food and Drug Administration (FDA) has granted Qualified Infectious Disease Product (QIDP) and Fast Track designations for KBP-7072, a new generation tetracycline for resistant bacterial infections.

KBP-7072 obtained the QIDP and Fast Track designations based on treatment of community-acquired bacterial pneumonia (CAP), which affects millions of people each year, more and more were due to resistant bacteria. "Bacteria resistant to multiple classes of antibiotics are becoming a real threat to human society." said Dr. Zhenhua Huang, Chairman of KBP BioSciences. "We started our journey years ago with KBP-7072. QIDP and Fast Track designations are good confirmation for our work. KBP-7072 can be an important treatment for CAP and other bacterial infections in the future."

The QIDP designation makes KBP-7072 eligible to certain incentives provided under the Generating Antibiotic Incentives Now Act (GAIN Act) of 2012, including Priority Review and eligibility for an additional five-year exclusivity under the Hatch-Waxman Act. Fast Track designation confers expedited development and regulatory review of drugs intended to treat serious or life-threatening conditions where there are significant unmet medical needs.

In addition to CAP, there are many infections which become life-threatening due to the increasing problem of drug-resistant bacterial pathogen. KBP-7072 is being developed for several indications.

About KBP-7072

KBP-7072 is a new generation broad spectrum antibiotics aimed at multi-drug resistant bacteria. In addition to major resistant strains such as MRSA, PRSP, and VRE, KBP-7072 is highly potent against *Acinetobacter*, a Gram negative pathogen. The bacterium is increasingly common in hospital and community settings causing high mortality rate. There is no effective mono- or combo-therapy for this deadly pathogen. KBP-7072 has good PK profile, available in both oral and injectable formulations, making it ideal for various infections. Phase I trial in the US showed that KBP-7072 was safe and generally well tolerated. The oral formulation has good drug exposure, and long half-life in human. No GI adverse events were observed at the highest dose tried.

About KBP BioSciences

KBP BioSciences is a clinical stage biotech company dedicated to research, development and commercialization of innovative medicines for the global market. The company's three clinical stage compounds have all obtained US FDA IND approvals.

KBP has developed a deep pipeline focused on meeting unmet medical needs globally. The company devotes its resources in three therapeutic areas, inflammation & autoimmune diseases, organ protection, and antibiotics. KBP has built a proprietary R&D platform aimed at discovery and development of global first-in-class compounds. The platform consists of a compound library which is

the basis of new compound discovery; a bacterium library aimed at multi-drug resistant bacteria; and *in vivo* pharmacology platform for screening and testing new compounds.

Headquartered in Jinan, China, KBP BioSciences established its US affiliate in Princeton, New Jersey, which is responsible for clinical development and registration. The management team has decades of combined experiences in drug development and registration. We work with a world-class scientific advisory board to advance new therapies for significant unmet medical needs.

Invented in China for the world.

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（济南和普林斯顿）亨利医药今天宣布，美国食品药品监督管理局（FDA）已经为KBP-7072（一种临床阶段的新一代抗耐药性细菌感染的四环素）授予了合格传染病产品（QIDP）和快速通道(Fast Track)认证。

KBP-7072获得这两项认证是基于其治疗社区获得性细菌性肺炎（CAP）的适应症。CAP传播广泛，影响巨大，每年有数百万人罹患该病症。亨利医药董事长黄振华博士说，“多重耐药细菌正在成为人类社会的真正威胁，我们多年前开始KBP-7072的研发工作 QIDP和Fast Track 两项认证是对我们工作的良好认可 KBP-7072 可能会成为治疗社区获得性细菌性肺炎及其他感染的重要手段。”

QIDP认证来源于美国2012年鼓励抗生素开发（GAINS）法案。经QIDP认证药物享有多重优惠政策，包括FDA优先审批（Priority Review）以及Hatch-Waxman法案规定的附加5年行政保护期。FAST TRACK 是为针对严重和致命疾病的药物提供优惠政策，为有巨大未满足临床需求的治疗领域提供新的治疗手段。FAST TRACK认证的药物享有FDA加快的临床和审批速度。

除了CAP，耐药菌还造成许多其他感染，威胁患者生命。亨利医药正在开发KBP-7072其他多种以耐药菌感染导致的适应症。

关于KBP-7072

KBP-7072是新一代针对耐药细菌的广谱抗生素，对包括MRSA PRSP VRE等主要耐药菌均有很高的活性，在已有报道的化合物中对不动杆菌的活性最强。不动杆菌在临床上的

分离率越来越高，目前没有有效的治疗药物，即使联合用药也无法解决现有的问题，导致死亡率高，对人类健康造成重大威胁 KBP-7072还有良好的PK特点，既可以口服给药，也可以注射给药，拓宽了适应症的范围。已经完成在美国的I期临床，证明KBP-7072口服吸收好，半衰期长，安全性高，耐受性良好，即使在最高剂量下也未观察到胃肠道副反应。

关于亨利医药

山东亨利医药科技有限责任公司（KBP BioSciences）是一家致力于国际化创新药物研发的公司。所有新药均通过FDA申报，并且率先在美国开展临床，迄今已经有3个药物获得FDA 批准进入临床试验。

亨利医药以临床未满足的需求为新药的出发点，专注于包括炎症和自身免疫性疾病、器官保护以及多重耐药细菌感染为主的三个治疗领域。公司经过多年积累建立了三个技术平台：化合物库、菌种库以及药理实验技术平台，化合物库是得到具有独特临床特点新药的分子基础，菌种库是找到治疗临床无药可用的多重耐药菌的生物基础，药理实验技术平台是筛选独有临床特点药物的生物基础。三个技术平台可以充分支持全球首创新药（First-in-class 的国际化研究和开发。

亨利医药中国公司位于济南，美国公司位于美国新泽西的普林斯顿，有资深的后期临床以及注册团队，负责公司新药在美国的临床开发以及注册工作，并且在治疗领域有全球顶级的专家团队共同参与，一起解决全球临床未满足需求。

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