Licensor – 벤처회사, 발명자 대학교수, 특허권자 대학, 연구소 vs 제약회사 - Licensee 사이 바이오신약 후보물질 특허기술 라이선스 계약서에서 라이센시의 임상시험 수행 등 개발의무 관련 간략한 방식의 계약조항 샘플

1.3 "**Commercially Reasonable Efforts**" shall mean the efforts, expertise and resources normally used by a Party to develop, use, Manufacture and commercialize a product owned by it or to which it has rights, which is of similar market potential at a similar stage in its development or product life, taking into account issues of safety and efficacy, product profile, difficulty in developing the product, competitiveness of the marketplace for the product, the proprietary position of the product, the regulatory structure involved, the availability and level of reimbursement for such treatment by Third Party payors or health insurance plans, the potential total profitability of the applicable product(s) marketed or to be marketed and other relevant factors affecting the cost, risk and timing of Development

and the total potential reward to be obtained if a product is commercialized.

7.1 **Research and Development Efforts**. The Licensee Kite shall use its Commercially Reasonable Efforts to conduct such research, development and preclinical and human clinical trials as are necessary to obtain regulatory approval to manufacture and market Licensed Products, and shall use good faith efforts to obtain regulatory approval to market, and following approval to commence marketing and market each such Licensed Product in such countries as Kite determines are commercially feasible. Kite, shall be responsible, at its sole cost and expense, for the development of Licensed Products in the Field. Kite, shall be responsible for: clinical trials with respect to the Licensed Products and filing required regulatory submissions and dealings with Regulatory Authorities with respect to Licensed Products. Kite shall also be responsible for reporting to the appropriate regulatory authorities adverse events related to Licensed Products as required by applicable law. Kite, shall also be responsible for communications with the FDA regarding such filings and Licensed Products; provided that Cabaret shall be consulted regarding any discussions or meetings with the FDA regarding Licensed Products, and following each meeting between the FDA and Kite regarding a Licensed Product, Kite shall provide Cabaret with a written summary of such meeting. Kite undertakes to use its Commercially Reasonable Efforts to

ensure that the Licensed Products marketed by it will, and it shall, in carrying out its obligations hereunder, comply with all legal requirements. Kite shall notify Cabaret within [*] after Kite becomes aware of the First Commercial Sale of a Licensed Product in each country. Kite shall have the right to perform all such obligations on its own behalf, or through an Affiliate, Sublicensee or contractor (which shall constitute performance by Kite hereunder).

7.2 **Records**. The Licensee Kite shall maintain records, in sufficient detail and in good scientific manner, which shall reflect all work done and results achieved in the performance of its research and development regarding the Licensed Products.

7.3 **Reports**. Within [*] following the end of each June and December during the term of this Agreement, the Licensee Kite shall prepare and deliver to the Licensor Cabaret a written summary report which shall describe (a) the research performed to date employing the Licensed IP Rights, (b) the progress of the development, and testing of Licensed Products in clinical trials, and (c) the status of obtaining regulatory approvals to market and its commercialization activities for Licensed Products. Kite promptly shall notify Cabaret upon

the initiation of any formal investigation, review or inquiry of Kite by regulatory authorities or governmental authorities concerning (i) non-clinical or clinical research relating to a Licensed Product; or (ii) the distribution, promotion or sale of a Licensed Product.