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GSK's Centres for Excellence in External Drug Discovery

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Abstract

The GSK Centres of Excellence for External Drug Discovery (ceedd) is the first team of about 25 people in GSK R&D to be completely externally focused with no internal programs to manage, working across all therapy areas, with the task to form multi-program, risk reward sharing alliances. A ceedd alliance can include programs starting at any point in development from target to clinical proof of concept (PoC). The ceedd effectively virtualizes a portion of the GSK pipeline. Through the ceded, partners have access to GSK's expertise across therapy areas, including technology and drug development specialists such as in experimental medicine, biomarkers, and imaging. In addition, partners may gain access to GSK's large compound screening library and genetic research tools.

1.0 Introduction

Soon after the merger of GlaxoSmithKline (GSK) in 2000, GSK identified that R&D was best done in smaller more productive units and introduced the Centres of Excellence for External Drug Discovery (ceedd).
The ceedd is the first team of about 25 people in GSK R&D to be completely externally focused with no internal programs to manage, working across all therapy areas, with the task to form multi-program, risk reward sharing alliances. A ceedd alliance can include programs starting at any point in development from target to clinical proof of concept (PoC). Generated from an innovative platform technology, GSK can have an exclusive right to option these programs at clinical PoC. (GSK CEEDD, 2011) However, each partner company retains autonomous control and responsibility over the pre-clinical development phase of their product.

2.0 The Partners

The ceedd combines GSK's Alternative Discovery Initiative (ADI) with the R&D concept of the Centres of Excellence for Drug Discovery (ceedds) to effectively harness talent and focus on drug discovery. The ADI partnerships with biotechnology companies and other pharmaceutical companies were created to explore different approaches to drug discovery. (GSK CEEDD, 2011)

An internal management team is responsible for delivering compounds with proof of therapeutic concept through partnerships with biotechnology companies, small- and mid-sized pharmaceutical companies, and academic institutions. (Outsourcing Pharma, 2005) The ceedd is a small, dedicated team that contributes to the GSK pipeline solely through the efforts of its external alliances. Essentially, the ceedd virtualizes a portion of the GSK pipeline. Through the ceedd, partners have access to GSK's expertise across therapy areas, including technology and drug development specialists such as in experimental medicine, biomarkers, and imaging. In addition, partners may gain access to GSK's large compound screening library and genetic research tools. (Forward Thinking, 2009; GSK CEEDD, 2011)

According to Mustafa Noor, Vice President, Head of Clinical Development, "…by complementing the existing capabilities of innovative biotechnology companies with multidisciplinary expertise and access to these extensive resources, the ceedd provides the fuel to drive transformative science forward." (GSK CEEDD, 2011)

To date, GSK has engaged in 9 alliances, and seeks to engage in others, starting at any point in the development path. Alliances include:

ChemoCentryx, Chroma Therapeutics, CoNCERT Pharmaceuticals, Max Planck Institute (MPI) of Biochemistry, OncoMed Pharmaceuticals, Prosensa, Ranbaxy, Targacept, and Theravance. (GSK CEEDD, 2011) (Table 1)

3.0 The Open Innovation Model

For companies that partner with GSK's Centre of Excellence for External Drug Development (ceedd), they have access to drug development experts, the full suite of scientific and technical expertise and global preferred suppliers used by GSK through Scinovo. GSK formed Scinovo in 2009 as an internal operating unit, which serves as the central hub of GSK's non-clinical development activities. (ceedd, 2010; ceedd, 2011)

When GSK created its Centre of Excellence for External Drug Discovery (ceedd) it commenced experimenting with a new type of model for biotech alliances. This new model was designed to provide companies with funding to drive early-stage science, while at the same time combining their scientific know-how with GSK's global network. Frequently referred to as "option-based deals," these phased financing agreements were ultimately designed to share the risk associated with drug discovery and development, while tapping into each partner's core competencies. Two geographic centers in the US and the UK are thought to enable for faster decision-making. (ceedd, 2010) (Figure 1)

When a company signs an agreement with the ceedd, the company has the option to access a range of GSK experts or services. For example, if the partner company is attempting to figure out how best to create a molecule that is more readily absorbed or how to design a non-clinical study protocol, Scinovo experts serve as consultants. If the company needs to find vendors that are capable of meeting certain quality standards or who meet specific criteria, Scinovo offers access to pre-screened

Alliance	Formed	Goal
ChemoCentryx	**2009**	To develop and market novel medicines targeting four chemokine and chemoattractant receptors for the treatment of a variety of inflammatory disorders.
Chroma Therapeutics	**2009**	Using chromatin biology to create cancer and inflammation treatments.
CoNCERT Pharmaceuticals	**2009**	Deuterium-based chemistry for novel therapeutic development.
Max-Planck Institute (MPI)	**2010**	Exploiting kinase biology to develop novel medicines for the treatment of type II diabetes.
OncoMed Pharmaceuticals	**2007**	Nine programs against novel cancer stem cell targets for oncology indications.
PROSENSA	**2009**	Focusing on RNA-modulating therapeutics for genetic neuromuscular and neurodegenerative disorders.
Ranbaxy Laboratories Limited	**2003**	Exploiting Ranbaxy's medicinal chemistry expertise.
TARGACEPT	**2007**	Five programs against neuronal nicotinic receptor (NNR)--targets across a range on neurological disorders.
Theravance	**2003**	Small molecule medicines development across a number of therapeutic areas including respiratory disease, bacterial infections and gastrointestinal disorders.

Table 1: Current ceedd Partners and Goals

Source: ceedd, 2010; ceedd, 2011.

contractors and laboratory facilities. However, the decision to work with Scinovo rests solely with the partner company. Furthermore, there may be options to contract the work with GSK's internal research teams.

To date, each ceedd partner company has worked with Scinovo in different ways—including Scinovo consultation resolving PK variability in animal studies through formulation strategies, understanding novel lesions in toxicology studies to facilitate further development of the specific molecule, enhancing a chemical synthetic route by identifying efficiencies, reducing costs of starting materials and clinical costs. (ceedd, 2010; ceedd, 2011)

4.0 Alliance with Ranbaxy

GSK and Ranbaxy—a generics company—came together through the ceedd in 2003 to broaden the therapeutic scope of their previous collaborations and build upon the expertise both within Ranbaxy and within GSK. Ranbaxy offers unique medicinal chemistry expertise and novel approaches to drug discovery. GSK can complement these skills by providing feedback on commercial areas of value and development planning expertise. (ceedd, 2011; Ranbaxy, 2008)

As a result of this ceedd alliance, Ranbaxy announced in that its New Drug Discovery/Development Research (NDDR) team had achieved a significant landmark in its collaborative research program with GlaxoSmithKline. Ranbaxy had been able to initiate Phase I clinical studies on its lead compound for respiratory inflammation. Phase I studies would be conducted in India and Europe. After the successful completion of Phase-I studies. (Ranbaxy, 2008; Ranbaxy, 2009) Ranbaxy would receive a milestone payment for initiating Phase I studies and would also be responsible for conducting Phase II clinical studies through to Proof of Concept. After the successful completion of the Phase IIa studies, GSK would then have the option to conduct further development through to final commercialization. (Ranbaxy, 2008; Ranbaxy, 2009)

5.0 Outcomes

The Ranbaxy-GSK collaboration was expanded in February 2007. Under the original agreement, Ranbaxy conducted the optimization chemistry required to progress drug leads to the stage of candidate selection. Under the new agreement, Ranbaxy would advance leads beyond candidate selection to completion of clinical proof of concept. GSK thereafter would conduct further clinical development for each program and take resulting products through the regulatory approval process to final commercialization. Ranbaxy would receive milestone payments for a product developed by Ranbaxy and subsequently launched by GSK in multiple indications and up to double digit royalties on worldwide net sales. (PRNewswire, February 2007) Ranbaxy would retain the right to co-commercialize the products in India. The new milestones and royalties would apply both to future drug discovery programs and to the two programs currently ongoing at Ranbaxy, that were commenced under the original agreement with GSK. The alliance anticipates focusing on multiple therapeutic arenas including anti-infectives and metabolic, respiratory and oncology products. (PRNewswire, February 2007)

6.0 Expanding into Asia

Recently, GSK strengthened its commitment to emerging markets by establishing a number of partnerships specifically aimed at developing a strong product pipeline. Specifically, GSK formed the Asia Pacific, Japan and Emerging Markets (APJEM) R&D team of dedicated experts based within its R&D organization to focus on emerging

markets. APJEM R&D identifies internal and external opportunities and adds clinical development, formulation development, and regulatory expertise to regional product development. GSK continues to seek partnerships with companies who wish to develop their products for the emerging markets, but who may not have the in-house experience or resources—leveraging the wealth of expertise and resources that reside within GSK to bring quality medicines rapidly to people in these emerging markets. (Forward Thinking, 2009)

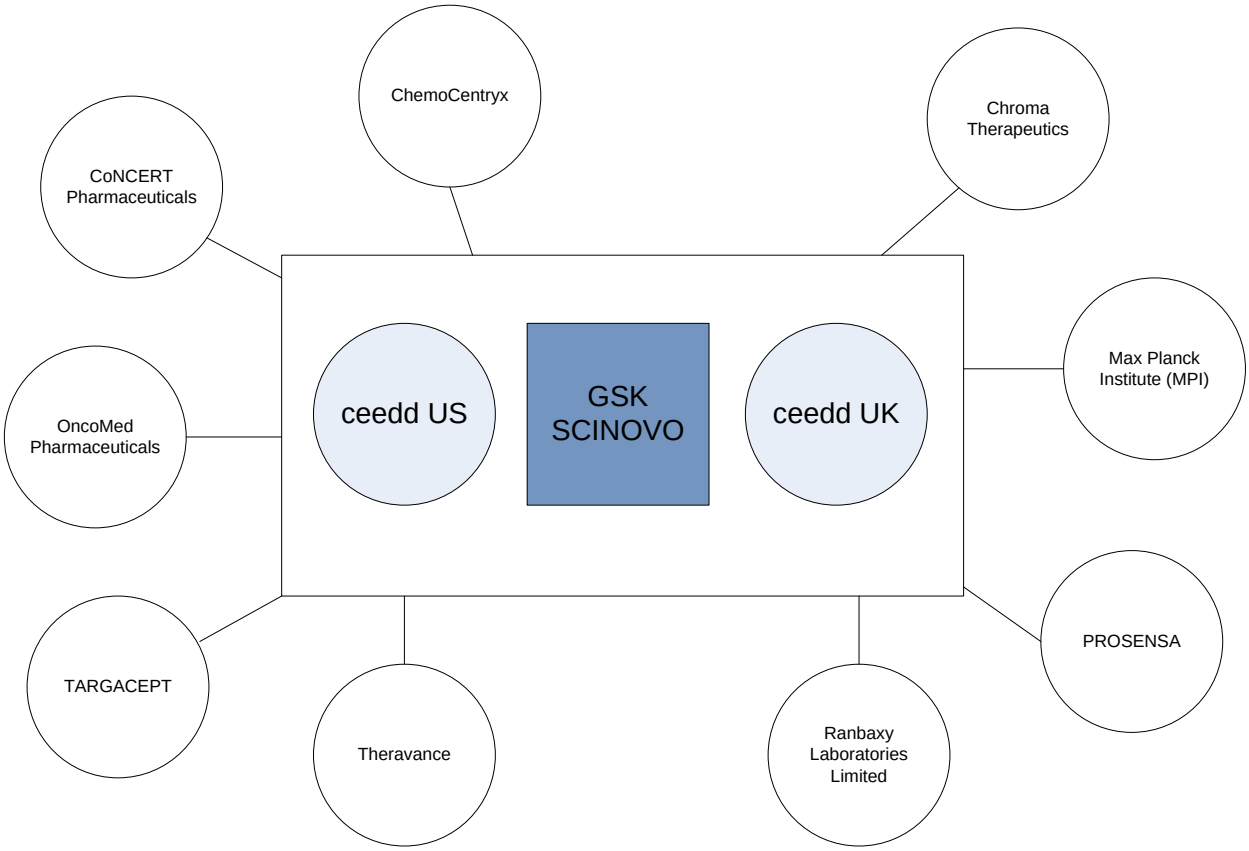

Figure 1: The ceedd Model

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