POSTER #129

The ImQuest*SUCCESS* Drug Development Platform: Enhancing Successful Drug Development Opportunities

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Understand Needs. Develop Solutions. Build Relationships.

ImQuest*SUCCESS*

*"The rapidly increasing costs of drug development are directly related to funding the costs of FAILURE……..successful product development requires an early understanding of the **efficacy, safety, and pharmaceutical properties** of a product."*

ABSTRACT

Successful drug development is dependent on a variety of complex variables that have been difficult to assess and thus poor drugs are often advanced to clinical testing that might have been deprioritized upon detailed preclinical evaluation. The rising costs associated with successful drug development are in large measure a result of the need to finance drug development failures. We have developed a platform of assays that allow the rapid delineation of critical preclinical properties of therapeutic and preventative antiviral, antimicrobial and anti-fungal drug candidates, as well as anti-cancer products. The ImQuestSUCCESS platform is built upon the necessity of building the strongest possible foundation of preclinical data that will allow rationale decision making as to the likelihood of clinical success and the prioritization of compounds for continued advanced development. The three keys to the ImQuestSUCCESS platform include appropriate evaluation of the efficacy, safety and pharmaceutical properties of a potential product, all of which may be evaluated in a cost-effective manner prior to the investment of significant R&D funding in the advanced stages of preclinical and clinical product development. The ImQuestSUCCESS platform has been built to evaluate both therapeutic and prevention products against infectious viruses, bacteria and fungi and provides a rapid data-driven evaluation of the relative development potential of a given product. Efficacy assays are designed to reveal the therapeutic index of test products in the biological matrices in which they must act using *in vitro* and *ex vivo* assays that measure the range and mechanism of action of test compounds, their ability to select for resistant organisms, and their ability to function in combination with other products (including those used to treat/prevent other infectious organisms). A hallmark of our ImQuestSUCCESS platform is the definition of the tissue concentration of a product required at the site/target of infection required to totally suppress or sterilize the infection site. In addition to product efficacy, the ImQuestSUCCESS platform also provides critical measurements of product safety through the use of assays which measure *in vitro* and *ex vivo* cytotoxity, compound permeation and compound metabolism, including stability, enzymology, and activation, as well as measures of *in vitro* and *ex vivo* pharmacokinetic and pharmacodynamics (PK/PD) properties. Finally, ImQuestSUCCESS evaluates important pharmaceutical properties of a test compound to assure that it will be possible to effectively formulate and deliver the compound to achieve optimal PK/PD and attain sterilizing concentrations at the site of infection. The ImQuestSUCCESS platform thus provides a foundation of essential efficacy, safety and pharmaceutical property data that drug developers may utilize to rationalize continued financial and manpower investments in products with enhanced potential for clinical success.

Enhance the probability of your product development *SUCCESS* with our customized *SENS* technology platforms

Product efficacy is evaluated using high content bioassays which employ relevant target cells for virus infection or appropriate reference and clinical strains of virus, bacteria, or fungi to define the range and mechanism of action of new drug products. These evaluations address the FDA *Points to Consider* Guidelines for the development of antiviral, antimicrobial, or anti-cancer compounds. Our ***SENS*** platforms include diverse panels of organisms (wild-type and drug resistant) for the evaluation of products for both therapeutic and prevention use (topical microbicides).

- ✓ **ViroSENS** for evaluation of anti-viral efficacy
  - HIV-1 and HIV-2
  - HBV
  - Flaviviruses (HCV, dengue virus, YFV)
  - Respiratory viruses, (influenza and RSV)
  - Enteric viruses
- ✓ **PrevenSENS** for the evaluation of products to prevent the transmission of sexually acquired infections
- ✓ **MicroSENS** for evaluation of anti-microbial efficacy
- ✓ **OncoSENS** for the evaluation of anti-cancer efficacy

Product safety is evaluated through a variety of *in vitro* and *ex vivo* assays which quantify the toxicity and off-target effects of potential drug products on host cells and tissues. These cells and tissues would include the targets of the virus as well as other hematologic and solid tissues that might yield biomarkers of product toxicity. Though not necessarily predictive of *in vivo* toxic effects or potential safety issues, developers may prioritize products based on these safety signals or develop safety programs to investigate potential problematic areas for successful development.

- ✓ **ToxiSENS** for the evaluation of product safety
  - *In vitro* cell and tissue toxicity
  - Immunotoxicity
  - Permeability
  - Metabolism
  - Drug-drug interactions
  - Pharmacokinetics and pharmacodynamics

Product pharmaceutical properties address the feasibility of potential new products to rapidly and efficiently evaluate the formulation potential and identify the formulated dosage form of an new chemical entity. It is critical to implement formulation and delivery evaluations early in the drug development process to reduce the risk, time, and cost of moving a drug to clinical studies.

- ✓ **PharmaSENS** for the evaluation of a product's pharmaceutical properties
  - Drug dosage formulations
  - Analytical services
  - Physicochemical characterization
  - *In vitro* drug release
  - Product stability

ImQuest***SUCCESS*** data are reported in the following presentations at this ICAR:
Oral presentations: 3 and 21
Poster presentations: 44, 45, 55, 77, 106, 107 and 128

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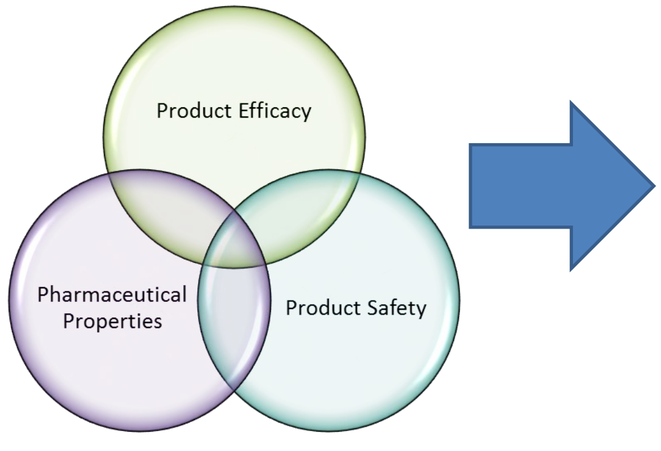

- Successful drug development requires a highly iterative process of drug design and testing that ultimately yields a drug candidate with superior efficacy and potency, with minimal safety/toxicity issues, and which can be formulated for effective delivery to the target tissue.
- The efficacy, safety, and pharmaceutical properties of new compounds thus must be critically evaluated to optimize the potential for clinical SUCCESS.