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I am a trained medicinal chemist currently working in the laboratory of Dr. Gabriela Chiosis at Memorial Sloan Kettering Cancer Center as a research faculty. During the past ten years I have been working to develop novel small-molecule therapeutics targeting disease-specific variants of heat shock proteins (HSPs), such as HSP90, GRP94 and HSP70. These variants are involved in cell stress and survival and may play a critical role in the development of cancer, neurodegeneration and potentially other diseases. We use a chemical biology approach to investigate HSPs with the ultimate goal of translating agents into the clinic for the treatment of human diseases. In this regard, my expertise in designing and synthesizing small molecule inhibitors as well as biological probes for these targets has been critical to the successful outcomes of our research projects. I have an extensive knowledge of chemistry and its proper application for establishing structure activity relationships (SAR) as well as a keen understanding of what is required to transform a molecule into a drug. I have also acquired knowledge of cancer biology and a belief that it is the biology which drives the successful development of any drug discovery program. I believe that my qualifications and experience to date put me in a position to uniquely impact the field and to potentially provide cures to cancer.

Efforts thus far have resulted in one agent, PU-H71, a potent inhibitor of HSP90-incorporating epichaperomes, to enter clinical trials in patients with advanced solid tumors, lymphoma and myeloproliferative disorders (NCT01581541, NCT01393509, NCT03166085, NCT03373877 and http://www.samustherapeutics.com/wp-content/uploads/Samus-PU-H71-ODD-FP…) and another PU-AD which is expected to enter clinical evaluation this year in AD and CTE, under Samus Therapeutics Inc. sponsorship (http://www.samustherapeutics.com/). Additionally, a radiolabeled version of this agent, ^{124}I-PU-H71, has also entered clinical trials as a non-invasive means to determine tumor pharmacokinetics and intra-tumoral concentration and to detect the target expressing tumors by PET imaging (NCT01269593). Similarly, a radiolabeled PU-AD has entered clinical evaluation to detect the HSP90-incorporating epichaperomes in diseases of the CNS (NCT03371420 and http://www.samustherapeutics.com/wp-content/uploads/Samus-Corporate-Upd…). Furthermore, my direct involvement in these clinical trials have given me a more profound understanding of the term “bench to bedside”. My research has also contributed towards the discovery and optimization of a novel class of small-molecule HSP70 inhibitors which are currently undergoing evaluation for efficacy in pre-clinical models of cancer. To support these efforts, I have received two prestigious post-doctoral fellowships from Komen for the Cure and Department of Defense, for the preclinical discovery and development of HSP70 inhibitors in breast cancer with the ultimate goal of developing an HSP70 inhibitor suitable for the treatment of human diseases. A lead

molecule LSI137 has been recently identified from this series, and this agent is soon to enter IND-enabling studies.

Our lab has made a number of important discoveries regarding the nature of chaperones in cancer cells that have fundamentally altered our view of them as a cancer target. We found that chaperones such as HSP90 and HSP70 together with cochaperones and cofactors are incorporated into stable complexes termed epichaperomes. Cancer cells that are dependent upon the epichaperome for survival are vulnerable to agents which target them, and as a result the epichaperome represents a novel target in cancer. Our work has dramatically altered the way we approach the discovery and development of agents which target chaperome components such as HSP90 and HSP70 and will have profound implications in their clinical development.

With my extensive knowledge and experience in cancer drug discovery and development, especially as it is related to disease-forms of heat shock proteins, I feel I am well suited to continue making important contributions that will fundamentally improve cancer treatment.

During this period I have also been involved in a multitude of collaborative efforts. I have provided our collaborators with mg to gram amounts of small molecule inhibitors for which I have developed suitable scale-up synthetic methods, formulations for their proper in vivo use and have established conditions for their proper use and storage.

Drug discovery: Challenges of making a drug

Drug discovery is a long and difficult endeavor but can be extremely rewarding when such efforts lead to the clinical translation of important discoveries that can potentially benefit many. Such a process generally begins with the exciting discovery of a protein in a biological pathway that can potentially be modulated through the use of a small molecule. If structural information is available on the protein of interest, this can be used to guide structure based drug design (SBDD). In this approach, ligands are designed to fit within a binding pocket on the protein and computationally evaluated for maximal interaction with the protein. Selected compounds can then be chemically synthesized and evaluated in assays designed to measure the ability of the compound to bind. The information from these initial studies can be used to confirm binding and validate the computational design of ligands, which in turn can be used to design more potent analogs. In a complementary approach, the availability of biological assays can be used to screen large libraries of compounds referred to as high-throughput screening (HTS). Such screens can result in interesting “hits”, which may serve as useful probes for further biological investigations, however, they rarely have the desired properties suitable for a drug. Whether “hits” are obtained by SBDD, HTS or by other means, it is rare that these are suitable as a drug and require extensive optimization into potent lead molecules and further into clinical candidates. These efforts are typically extremely challenging and expensive. Hits obtained from initial screens do not have the potency nor the ideal pharmacokinetic (PK) properties to be suitable as drugs. These “hits” have to be chemically modified through the synthesis of

properties to be suitable as drugs. These "hits" have to be chemically modified through the synthesis of numerous analogs that improve potency while at the same time consider the potential PK effects. Therefore, a parallel approach in analog development that considers both potency and PK properties is the current paradigm in drug discovery that offers the best chance for the successful development of a drug.

Drug discovery is a very expensive process and it is estimated that it costs approximately $800 million to successfully bring an anti-cancer drug into market. Therefore, the stakes are very high and failures or even setbacks can have serious consequences for the economic well being of any organization involved in drug discovery. While it used to be the case that most drugs in clinical trials would fail as a result of poor absorption, distribution, metabolism and excretion (ADME) properties, now the primary reasons for drug failure is a lack of efficacy and/or unacceptable toxicity. This change has occurred as a result of a greater appreciation of the importance of ADME through the implementation of numerous assays which have greatly improved our ability to predict PK in humans.

Early screening for ADME properties has become the norm in the pharmaceutical industry. The investigation of ADME and a good understanding of the physicochemical properties (solubility, stability, etc.) of candidates as well as potential toxicity issues early in the drug discovery process can result in substantial savings in both money and time. The results from these early studies can guide in making crucial go or no-go decisions. Early ADMET studies eliminates wasted development effort on unsuitable compounds and can shift medicinal chemistry efforts towards more promising areas of development.

Drug discovery will always be a risky business, however, these risks as well as the time involved can be minimized if the liabilities of a molecule are known and adequately addressed early in the process. As a scientist, I can think of no more satisfying achievement that the translation of discoveries made at the bench into useful therapeutics for the treatment of disease.

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