Plants have a long history of use in Medicine and have been used by all cultures or ethnic groups throughout the history of humanity. They have always been a common source of medicine either in the form of traditional preparations or as pure active principles. Their use is similar to the way modern pharmaceuticals are used today. Many botanical medicines contain curative principal active substances, which have proven to be valuable as primary or supplemental therapies when carefully applied. Plants are an essential source for the discovery of novel pharmacologically active compounds, with many blockbuster drugs being directly or indirectly extracted from plants. Medicinal plant drug discovery continues to provide new and important leads against various pharmacological targets including cancer, HIV/AIDS, Alzheimer’s, Malaria and Pain. Approximately 75% of the new chemical entities (NCE’s) reported between 1981 and 2006 resulted from studies of natural products.

Botanical drug development is challenging as the inherent nature of these products is that they are generally, extracts of plants rather than chemically pure compounds. The objective of this presentation is to discuss botanical drug development from lead identification, optimization and development to Nonclinical and Clinical Drug Development and regulatory submission and review to marketing approval.

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