

**Key words:** *Ganoderma lucidum*, polysaccharides; lymphocytes; macrophages; costimulatory molecules

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## Standardization, preclinical and clinical evaluation of epimedium extracts for post-menopausal osteoporosis, breast and prostate cancers

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**Abstract:** Estrogens are critical for bone health and the development of breast and prostate tissues. At menopause, our cohort studies show that naturally occurring estrogens in the body protect against osteoporotic hip fractures, but can also increase the risk of breast cancer. Extracts of *Epimedium spp.* is widely used to treat osteoporosis and improve general health in post-menopausal women. Prenylated flavonoids from *Epimedium spp.* exert potent estrogenic effects making it an attractive alternative to estrogen replacement therapy for treatment of osteoporosis. Lead compounds from epimedium such as icaritin impact pro-osteoblastic, anti-osteoclastic signaling pathways in bone cells; and anti-tumour effect on nuclear receptors in breast and prostate cancer animal models. Oral administration of a *Epimedium spp.* extract in open-label, two-period, randomized, crossover study indicate significant *ex-vivo* effects on ER $\alpha$  and ER $\beta$ -mediated bioactivities and breast cancer cell proliferation. Challenges in the taxonomy, standardization and quality manufacturing of extracts suitable for pharmacokinetic, pharmacodynamics and efficacy studies in humans will be discussed.

**Key words:** epimedium extract; breast cancer; prostate cancer

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## Research on the research of pharmacological activities of traditional Chinese medicine

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**Abstract:** There are pharmacological aspects that multi-herbal traditional Chinese medicine (TCM) presents unique characters, to which conventional pharmacology research methods are not applicable. Few examples to mention: The generally lower in toxicity profiles for a TCM product makes the Pharm-Tox study methods need to be re-visited for validity, as the maximum tolerance dose (MTD) is very often unreachable by oral feeding, an injectable dose of unpurified herbal extract for toxicology check cannot be used for TCM products as well. Due to the so-called multi-components, multi-target phenomenon, the definition of "Pharmacological Effect" is hard to set and should be clearly re-defined for TCM. Plasma drug concentrations are normally low and hard to detect, especially the contribution of each chemical moiety to the apparent clinical effects is unknown, and generally observed concentration-response models (CR) are not applicable due to the mixture of hundreds of chemical moieties; Bioavailability studies from varies manufacture batches are not available but should be determined for drugs with potent active moieties and/or metabolites or has an narrow therapeutic window. However, the beauty is that, in the regulatory world, pre-clinical pharmacology data and the mechanism of action (MOA) information are valuable only if can be used to guide the drug development process. In this presentation, experiences gained during the process of developing a TCM product in the US and interactions with the US FDA are to