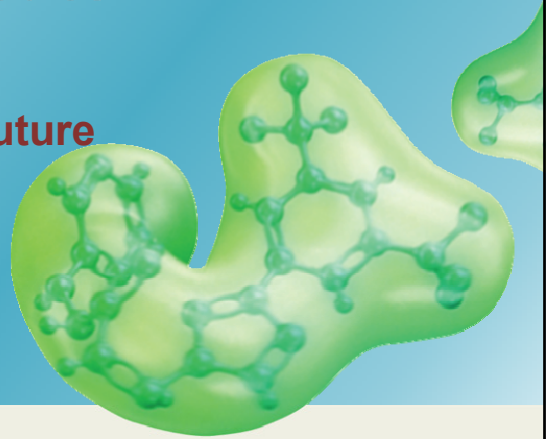




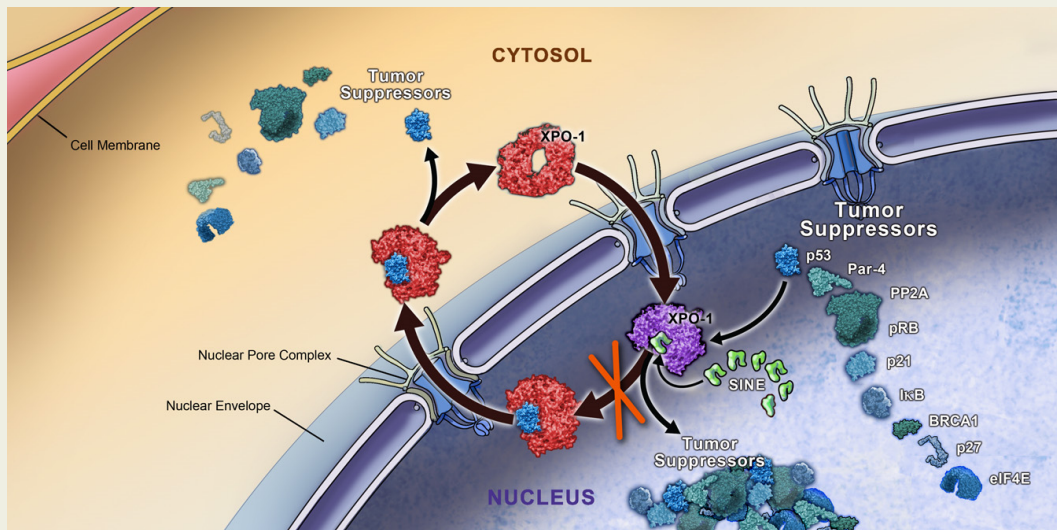
SME View on Clinical Trials in the Nordic Region and Vision to the Future

Mansoor Raza Mirza
Board of Directors, Karyopharm
Medical Advisor, Karyopharm

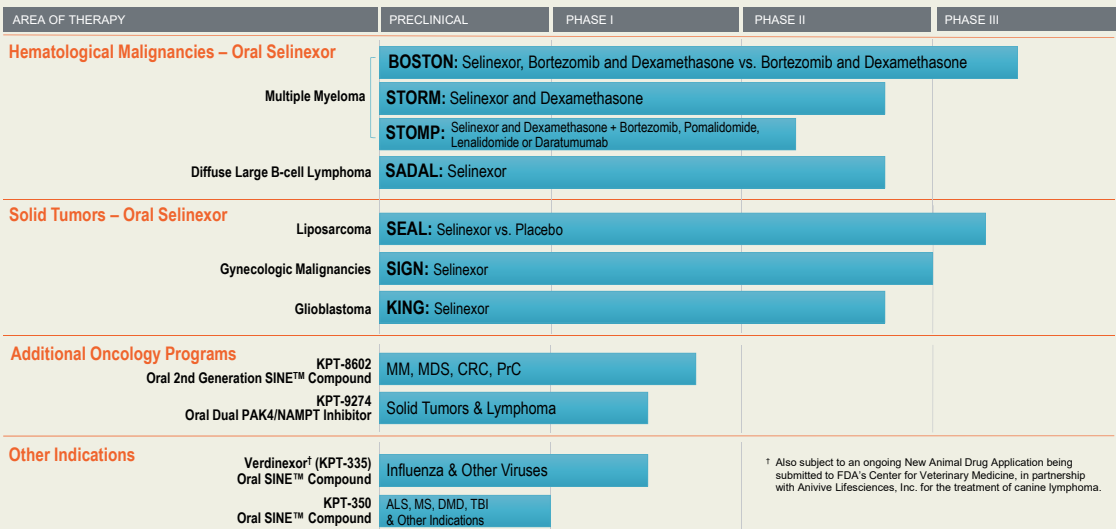


Targeting Disease at the Nuclear Pore

Selinexor: Novel Oral Anti-Cancer Agent Restores Tumor Suppressors & Reduces Oncoproteins



Karyopharm's Broad Therapeutic Pipeline

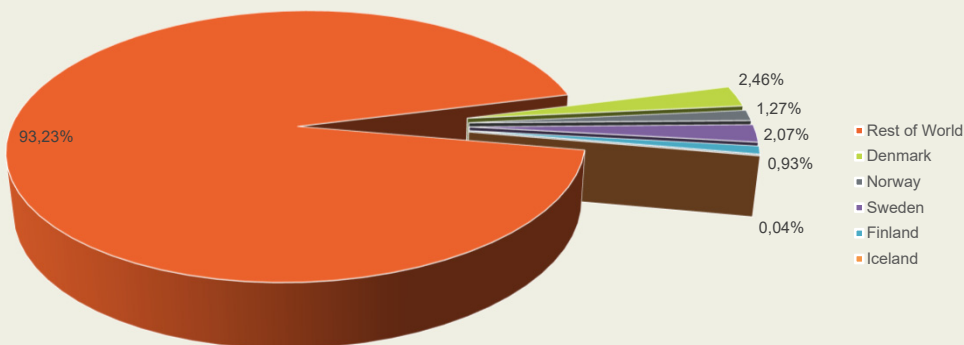


[†] Also subject to an ongoing New Animal Drug Application being submitted to FDA's Center for Veterinary Medicine, in partnership with Anivive Lifesciences, Inc. for the treatment of canine lymphoma.



Percentage of *Active Oncology studies in the Nordic Region

As growth and spending continue to lead in the oncology space through 2021, the major Nordic countries account for just **6.73%** of active clinical trials



*Active clinical trials include : recruiting, not yet recruiting, active not enrolling, and enrolling by invitation (clinical trials.gov)



GLOBAL INVOLVEMENT OF THE DHMA, GUIDANCE & SUPPORT

- DHMA initiated a for cause inspection to a PV vendor in Europe (ex Nordic)
- DHMA joined the local EU agency in the inspection of the PV vendor (ex Nordic)
- DHMA (on behalf of EMA) conducted a joint inspection with the FDA of the sponsor in the US
- Sponsor is working with both agencies to resolve all findings
- The DHMA is very cooperative providing direct access, continuous guidance and support to the sponsor on acceptable resolutions applicable for EU



Running Clinical Studies in Nordic Countries - Advantages

- Regulatory: knowledge and accessible rapporteurs
- Timelines: short regulatory timelines of 5 weeks
- Sites: well known and highly active clinical sites
- Language: most PIs and study teams speak and understand English fluently
- Centralized oncology treatment:
large catchment areas by a small, well defined number of sites
- Investigators: very experienced Investigators and site staff
- Ethics: relatively on time and cooperating ethic committees



Running Clinical Studies in Nordic Countries - Challenges

- Geography: sizable distances between sites
- Population: later phase studies (\geq Ph2b) usually need to include regions outside of the Nordic countries
- Budget perception: on the high side
- Enrolment statistics: can be improved

