

Kaleidoscope

Working for a Better Tomorrow



From the Directors Desk



Hello & Welcome once again!

Greetings from Naprod Life Sciences!!

I am sure you enjoyed reading our maiden issue of "Kaleidoscope". We were overwhelmed with the kind of response that we received from you which were truly encouraging.

I want to begin this issue with very happy news. Yes!! The long and anxiously awaited **EU GMP certification** for our manufacturing facility arrived eventually in the last week January 2019. Our entire team which put in their heart and soul towards this project is overjoyed and rightfully so. My heartiest congratulations to the entire Naprod team who logged it out to get this done. Needless to say, a plethora of business

opportunities will present themselves and we will be glad to offer our quality products and services to a wider geography. Our challenge will be to consistently living upto your high expectations and our hard-earned reputation.

This issue of Kaleidoscope has some interesting information on "Cancer Screening"; some news about a new class of drugs that is revolutionizing the cancer treatment called CDK (4&6) inhibitors; an alarming news about the rise of obesity related cancers in young adults in the USA; an interesting news item about the unlikely connection between iridium of extraterrestrial origin and cancer care.

I sincerely hope you enjoy reading this issue of "Kaleidoscope".
Best wishes!!

Mohan B. Jain
Managing Director
Naprod Life Sciences.



Section 1: NLS Bulletin



EU GMP accreditation induced excitement:

- Global Oncology plus supportive care market size is 133 Bn USD in 2017 up from 96 Bn USD in 2013.
- Excluding Biologicals and Products which are protected under patent, nearly 30 % (40Bn USD) of this market is open for countries that accept EU GMP.
- As expected, with Naprod successfully complying with EU GMP audit, Naprod's international business team is flooded with

enquiries from across the world for business opportunities in their respective countries/regions.

- These enquiries vary from site transfer projects, market access permission requests and also from Markets that implement referential pricing policies.
- Our internal teams are busy with market potential survey, streamlining documentations and doing production planning to meet the incremental demand. More information on this in subsequent issues...!

Other Developments:

- 2019-20 is a year of new product development for Naprod group of companies. This year we will be commercializing new products from different segments like anti-neoplastics, anesthetics, contrast media, parenteral nutrition and immunosuppressants.
- 25 product will be cleared in 2019-20 which include Lapatinib, Sorafenib, Bendamustine RTU*, Docetaxel RTU*, Topotecan, Polymyxin B, Colistimethate, Tacrolimus, Iohexol etc.
- All our new products will be available along with CTD dossier.
- Naprod plant PPB, Kenya Audit completed.

Section 2: News from around the world of Medicine



USPSTF Updates Cervical Cancer Screening Regimen

The U.S. Preventive Services Task Force (USPSTF) recommended primary care physicians screen women ages 21-29 every three years with cervical cytology. For women ages 30-65, the task force recommended screening with either cervical cytology alone every three years,

high-risk HPV (hrHPV) testing alone every five years, or hrHPV testing in combination with cytology (co-testing) every five years.

The task force also recommended against screening women younger than 21, women older than 65 who previously have been adequately screened, and women who've had a hysterectomy with removal of the cervix and who have no history of a high-grade precancerous lesion or cervical cancer.

Screening for cervical cancer saves lives and identifies the condition early, when it is treatable. There are several effective screening strategies available, so women should talk to their doctor about which one is right for them."

USPSTF Updates Prostate Cancer Screening Recommendations

Men aged 55 to 69 years should decide whether to undergo periodic PSA screening after a



discussion of the potential benefits and harms with their clinician. According to USPSTF, there is “moderate certainty” of a “small” benefit of reducing death with screening of men in this age group.

In addition, the USPSTF newly recommends against PSA screening for men older than 70 because the harms generally outweigh the benefits.

ESMO 2018: Major trial shows targeted drug – palbociclib – extends breast cancer survival

Women taking palbociclib together with hormone therapy lived seven months longer than those on hormone treatment alone – adding to previous data showing the combination could delay the disease's progression. The drug's benefit was stronger in women who had previously responded to hormone therapy – who lived 10 months longer with the combination treatment. The international PALOMA-3 clinical trial was led by researchers at The Institute of Cancer Research, London, and The Royal Marsden NHS Foundation Trust, and involved 144 research centres in 17 countries.

Abemaciclib receives additional approval as initial treatment for advanced breast cancer

Abemaciclib (Verzenio) in combination with an aromatase inhibitor (AI) as initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) advanced or metastatic breast cancer was approved by FDA in February 2018. This additional FDA approval marks the third

indication for abemaciclib within five months. In September 2017, abemaciclib became the first and only cyclin-dependent kinase (CDK) 4 & 6 inhibitor approved in combination and as a single agent in metastatic breast cancer. Specifically, abemaciclib was approved for use in combination with fulvestrant for the treatment of women with HR+, HER2- advanced or metastatic breast cancer with disease progression following endocrine therapy and as monotherapy for the treatment of adult patients with HR+, HER2- advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.

Ribociclib approved for Additional Indications in HR+/HER2- Advanced Breast Cancer

In July 2018, ribociclib (Kisqali) received approval for additional indications from the US FDA for women with hormone-receptor positive, human epidermal growth factor receptor-2 negative (HR+/HER2-) advanced or metastatic breast cancer. Ribociclib is now the only CDK4/6 inhibitor indicated for use with an aromatase inhibitor for the treatment of pre-, peri- or postmenopausal women in the US, and also is indicated for use in combination with fulvestrant as both first- or second-line therapy in postmenopausal women

Obesity-related cancers rising in young adults in the US

A new study finds rates are increasing for six of 12 cancers related to obesity in younger adults in the United States, with steeper increases in progressively younger ages and successively younger generations. Excess body weight is a known carcinogen, associated with more than a





dozen cancers and suspected in several more. Exposures to carcinogens during early life may have an even more important influence on cancer risk by acting during crucial developmental periods.

Simply shining light on 'dinosaur metal' compound kills cancer cells

A new compound based on iridium, a rare metal which landed in the Gulf of Mexico 66 million years ago, hooked onto albumin, a protein in blood, can attack the nucleus of cancerous cells when switched on by light, researchers have found. The treatment of cancer using light, called Photodynamic therapy, is based on chemical compounds called photosensitizers, which can be switched on by light to produce oxidising species, able to kill cancer cells. Clinicians can activate these compounds selectively where the tumour is (using optical fibres) thus killing cancer cells and leaving healthy cells intact.

Engineering a cancer-fighting virus

Hokkaido University, Japan researchers have engineered a virus that selectively targets and kills cancer cells. The virus, called dl355, has an even stronger anticancer effect than another engineered virus currently used in clinical practice.

Persistent sore throat could be larynx cancer warning

Gps should consider larynx cancer when patients report a persistent sore throat, particularly when combined with other seemingly low-level symptoms. A persistent sore throat combined with shortness of breath,

problems swallowing or earache is a greater warning sign of laryngeal cancer than hoarseness alone, new research concludes.

New 3D imaging technique reveals how pancreatic cancers start

The pancreas is a crucial organ that sits behind our stomach and plays a key role in digestion. It relies on a network of ducts linking it to other digestive organs, and the most common pancreatic cancers are found in the ducts. However, until now it has only been possible to see 2D slices of these ductal cancers, which contained an unexplained variety of abnormal shapes. By analysing developing cancers in 3D, researchers defined two distinct types of cancer formation originating from ductal cells: 'endophytic' tumours which grow into the ducts and 'exophytic' tumours which grow outwards. The researchers also applied the technique to other organs, and found that cancers in the airways of the lungs and ducts in the liver behave in the same way. This shows that the mechanism discovered is not specific to the pancreas and also applies to other cancers. Professor Andrew Biankin, Cancer Research UK's pancreatic cancer expert, says: "This technological breakthrough has the potential to unlock many unanswered questions of great importance in how we understand and treat pancreatic cancer. It's crucial we better grasp how these cancers behave from the earliest stages, to help develop treatments for a disease where survival rates have remained stubbornly low."

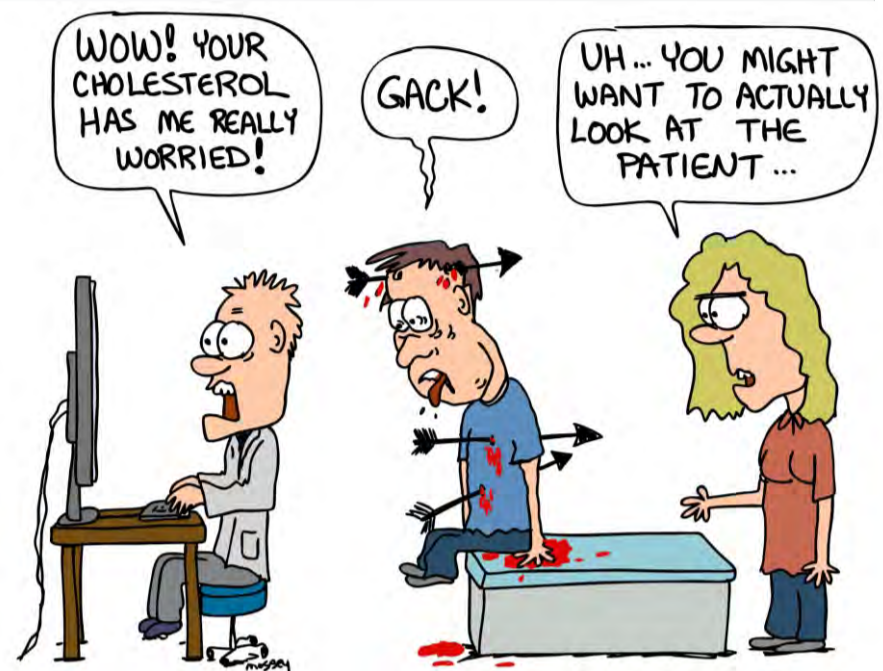




Section 3: Humor is the best medicine!!



**"Good news.
Your cholesterol has stayed the same,
but the research findings have changed."**



HENRY IS OVERJOYED WITH HIS CORRECTIVE SURGERY RESULTS



Sovereign in Oncology

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