Introduce your CTE Design Review Topic

- This week we'll be discussing CTE solutions. Now that you have selected a topic, introduce your CTE Design Review product to the class. Be sure to include the following information:
    - Product name
    - Company or research group developing the product
    - Current status of the product (i.e. in development, under clinical investigation, or FDA approved)
    - Problem the solution is solving
    - Brief description of one (1) solution that existed prior to the use/development of the new solution

- Respond to at least two of your classmates.

Due: Initial post - Sunday 11:59 pm, responses - Tuesday 11:59 pm

Instructor Note

Hi All,

Only one thread this week so you can interact with all the project topics for this semester.

* Please use one initial post for your project group (only one of the two group members should post), and list both names at the top of the post.

* It's helpful if your post title includes your group number and your project title.

* Each student should post two responses, like usual.

Dr. Nyberg

I am reviewing two products which I thought could complement each other. The first product is the neural-spinal scaffold, developed by InVivo Therapeutics, which promotes recovery in patients with thoracic AIS A traumatic spinal cord injury (no motor or physical sensation below the level of injury) between vertebra level T2-T12. In the first clinical trial some patients had an improvement on AIS scale [1,2], and FDA has approved the preclinical version of the scaffold [3]. The second product, OPC1, developed by Lineage Therapeutics, is an oligodendrocyte progenitor (OPC) cell therapy. OPCs are the source of myelinating oligodendrocytes which promote regeneration following SCI [4]. FDA has granted OPC1 the medicine advanced therapy (RMAT) designation. Lineage has completed a first study (SCIStar) with patients achieving 2 to 3 motor levels of improvement [5] and is currently conducting a PhaseI/IIa dose escalation study.

Different therapeutics and strategies exist to address SCI severe challenges and improve its repair, none of them are successful; and many are controversial.
Two neuroprotective drug therapies have been used for years to limit the neurotrauma of SCI: Methylprednisolone (MP) and Riluzole. MP, approved by the FDA, presents many complications including infection, hemorrhage and death [6]. So far there is no scientific evidence that riluzole (not approved by FDA for SCI), has significant effects for the recovery from SCI [7].

Sources:

[1] INSPIRE Study
[2] Theodore, Nicholas et al. "First Human Implantation of a Bioresorbable Polymer Scaffold for Acute Traumatic Spinal Cord Injury: A Clinical Pilot Study for Safety and Feasibility." *Neurosurgery* vol. 79,2 (2016): E305-12. doi:10.1227/NEU.0000000000001283
[3] Neural-Spinal Scaffold FDA Approval
[4] N. Li and G. K. K. Leung, "Oligodendrocyte Precursor Cells in Spinal Cord Injury: A Review and Update," *Biomed Res Int*, vol. 2015, p. 235195, 2015, doi: 10.1155/2015/235195.
[5] SCiStar study
[6] Methylprednisolone side effects
[7] N. Nagoshi, H. Nakashima, and M. G. Fehlings, "Riluzole as a Neuroprotective Drug for Spinal Cord Injury: From Bench to Bedside," *Molecules*, vol. 20, no. 5, pp. 7775–7789, Apr. 2015, doi: 10.3390/molecules20057775.