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To: Association for Creatine Deficiencies (ACD)
From : Carol Dutch, Senior Director, Patient Engagement
Date: Aug 2, 2016
Re: Q & A Statement regarding "cyclocreatine products" and explanation of pharmaceutical drug names

Dear ACD,
Thank you very much for your email, dated Aug 1st, posing the questions you have received from both your community along with the French advocacy group, Xtrodinaire. Below please find the two Q&A statements that you may share with your CTD community.

Best,
Carol

ACD Question: There are products containg cyclocreatine on the global market. Are they different from what Lumos Pharma is developing?

Lumos Pharma is aware that there are products being marketed that purportedly contain cyclocreatine. These products might be called "dietary supplements". Lumos has tested, via reputable laboratories, some of these "cyclocreatine products" and found that some of the products do not contain cyclocreatine, or the amounts of cyclocreatine were negligible.

In the United States, dietary supplements are not subject to the same degree of regulatory scrutiny as pharmaceutical products. Importantly, dietary supplements may not necessarily contain what they claim to contain, and the purity of the substance is nearly always far inferior to that of a pharmaceutical product.

Dietary supplements: According to the FDA, dietary supplement manufacturers and distributors are not required to obtain approval from the FDA before marketing dietary supplements. Dietary supplement companies are responsible to ensure that the product is safe and that any claims made about the products are not false or misleading.

Pharmaceutical drugs: According to the FDA, pharmaceutical drugs are required to undergo regulated clinical development designed to meet safety and efficacy standards. They are also regulated by the FDA to prove that the drug contains the active principle under very high standards of quality assurance and consistency.

ACD Question: Can you explain the difference between the name cyclocreatine and the name LUM-001, the new drug that Lumos is developing?

In the course of developing a new pharmaceutical therapy, there might be four different types of names assigned: a chemical name, a company designated name, a generic name, and a brand name.

1.Chemical name
When a novel chemical or biological therapy is developed, a chemical name is given.Based on the compound's chemical structure, the chemical name is a scientific name and is almost never used to identify the drug in a clinical setting. In our case, cyclocreatine's proper chemical name is: (2-Amino-4,5-dihydro-1H-imidazol-1-yl) acetic acid. Cyclocreatine is a commonly used synonym to make it easier to communicate (2-Amino-4,5-dihydro-1H-imidazol-1-yl) acetic acid.

2. Company designated name
A company that is developing a new drug will give it a company codename to identify it within the company.For example, LUM-001, is Lumos Pharma's company codename for the drug we are developing that contains cyclocreatine (2-Amino-4,5-dihydro-1H-imidazol-1-yl) acetic acid.

3. Generic name
The generic name, or International Non-proprietary Name (INN), is a commonly used, formal means to identify a drug during its useful clinical lifetime.INNs facilitate the identification of pharmaceutical substances or ingredients. Each INN is a unique name that is globally recognized and is public property. An INN is designated by the World Health Organization. LUM-001 does not yet have a generic name.

4. Brand name
As the clinical development of LUM-001 progresses, Lumos will choose a brand name, trade name or trademark. Under trademark law this name is owned by the company which has exclusive rights to use it. Note that a drug may have more than one brand name.
LUM-001 does not yet have a brand name.