# DIABETES RESEARCH



ISSN 2379-6375

Open Journal =

http://dx.doi.org/10.17140/DROJ-1-112

# **Opinion**

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Volume 1 : Issue 3 Article Ref. #: 1000DROJ1112

#### **Article History**

Received: June 25th, 2015 Accepted: July 1st, 2015 Published: July 1st, 2015

### Citation

Dimitrov D. Do we need new therapies for diabetes?. *Diabetes Res Open J.* 2015; 1(3): 75-76. doi: 10.17140/DROJ-1-112

# Do we Need New Therapies for Diabetes?

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Diabetes research and practice cluster (drug developers, payers, regulators and physicians) often (and especially in recent times) question the need of new therapies. Why would we need new therapies nowadays, when we have 9 classes (insulins, sulfonylureas, biguanides, meglitdes, thiazolidnediones, alpha-glucosidase inhibitors, DPP-4 inhibitors, SGLT2 inhibitors and GLP-1 receptor agonists), rapidly increasing number of biosimilars<sup>2</sup> and uncountable number of generics? Reasonable question. Does it make sense to invest billions of dollars in messy global cardiovascular outcomes trials (as requested by diabetes drug development guidelines<sup>3</sup>) or to play love attraction games with payers<sup>4</sup> so they "fall in love" with the "new" pill (most often combo with the good old metformin)?

Well....I believe someone is missing in this picture. Obviously, those four players forget the Patient. And the ability to ask a bit more simple and rational questions, such as "Do we have adequate glycemic control of diabetes in the presence of all those therapies"?

I know that such question would add "noise" in the discussion from the different parties returning back the ball to the patients, who do not have proper life style and as well as knowledge on the condition.<sup>5,6</sup> Question is: Could they?

To avoid entering a philosophical thoughtfulness that we do not live a perfect world, I will answer directly the main question of this Opinion. Yes, we desperately need breakthrough therapies for diabetes. Not therapies that mimic the current ones (long or ultra fast acting versions, combos or biosimilars). We need therapies that do not complicate the natural way of thinking (and living) by adding the next complex scheme (currently named "personalized").

At the end of the day, diabetes per se is loss of pancreas function and the only way to restore this loss is to develop therapies that restore pancreas cells.

Two companies pioneer the field: ViaCyte and Mesoblast. Though their approach is different they both target regenerative stem cells and I believe this is the future. Couple of other companies use iPS cells for different indications (just to mention BioTime, Inc [oncology and orthopaedics], Vericel Corporation [rheumatology and cardiomyopathy] among many others).

Major concern for all anti-diabetic therapies is cardiovascular safety profile. As a matter of fact, previous treatment recommendations for "intensified" control of diabetes pushed medical practitioners to lower blood glucose beyond physiological equilibrium<sup>8</sup> and this led to an end of decade era of dogmatic schemes – however a positive outcome – leading the current guidelines to more flexible framework.

ViaCyte has entered Phase II programme for T1DM using implantable subcutaneous devise, 9 following positive Proof of Concept studies.

While Mesoblast Allogeneic Mesenchymal Precursor Cells (MPCs) not only excel positive on glycaemia; they also promote additional heart and renal protective effects, which will be further tested in global Phase III trials.<sup>10</sup>

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ISSN 2379-6375

Open Journal 3:

http://dx.doi.org/10.17140/DROJ-1-112

#### **CONFLICTS OF INTEREST**

The author declares no conflict of interest.

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