Journal of Clinical Trials & Research
JCTR, 3(3): 195-196
www.scitcentral.com

ISSN: 2637-7373

Commentary: Open Access

Favipiravir Trial

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Received May 27th, 2020; Revised May 31st, 2020; Accepted June 02nd, 2020

ABSTRACT

Favipiravir is a useful drug in Covid-19. In 2012, USA Department of Defence awarded huge grant to the sponsor for clinical trial of this molecule for influenza. But what happened next is full of mystery. Author tries to throw some light on this subject.

INTRODUCTION

Recent pandemic has caught the world unaware but its speed of spread and devastation along with fatality is horrific. Question is naturally raised about how world leaders like USA and China prepared themselves for such viral infection of pandemic proportion. This is because strong defence and military organisation of many developed countries have dedicated wings of research which investigate this kind widespread infection which might well be act of terrorism. Hence, they should arrange for advance preparation against these presumed dangers. COVID-19 which is influenza of pandemic proportion is not any exception. There is much furore about efficacy and availability of hydroxychloroquine but only a little is known about availability of another molecule which if available could be of great help in this hour of need. This molecule is favipiravir. It was invented as the most useful drug for bioengineered pandemics. Though it was developed by Toyama Corporation of Japan, it was specially taken up by the Department of Defence of USA for its probable usefulness in bioterrorism era. A search for this drug and its present status was made and hence this write up [1].

DISCREPANCY

Wikipedia was naturally my preliminary search. The Wikipedia is not authentic and was proved by my general query to the molecule, Favipiravir. Their record frequently changed during the course of my repeated enquiry. Just few weeks back I saw that this drug was not approved at all by FDA. Then it said FDA has 2015 completed phase III trial. This is absurd. FDA never does trial. Hence, some vested interest is suspected to be playing behind the changes in Wikipedia record, though that is my personal feeling. Frankly, no truth was distributed by Wikipedia; this has however entirely changed afterwards and no FDA status was recorded at all, as if it was never placed before FDA and no trial was done in the USA. Recent access to Wikipedia however is entirely edited and they have raised this issue more or less properly.

Wikipedia reference showed an innocuous study, "a phase 3 Efficacy and Safety Study of Favipiravir for Treatment of Uncomplicated Influenza in Adults" – (T705US316) enlisted in ClinicalTrials.gov, Identifier: NCT02026349 [2].

NCT02026349

I saw it before, this trial detail; being in drug regulatory in India I was naturally trying to find when trial of this important repurposed drug of COVID-19 started first and how everything went. The trial of Favipiravir started in 2014 and was completed in 2015. But where is approval? And where is market authorisation? Nothing; there was nothing. There is no such entry of Favipiravir in whole FDA main website. It is stacked in archival section of FDA with huge documentation from where it is next to impossible to find what happened to the drug and what was its fate. So, I wrote to FDA twice, only to know that it is not possible to know anything because of federal confidentiality (personal communication). But they did inform me that all records are with sponsor and sponsor is Fujifilm. This is also not a fact. How could they say so?

The trial sponsor of Favipiravir in USA was never Fujifilm which we will see later. Trial was completed; that is the

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Citation: Boss CK. (2020) Favipiravir Trial. J Clin Trials Res, 3(3): 195-196.

information, the only substantial thing that clinicaltrials.gov could inform us. So, was it cancelled or disapproved by FDA or sponsor did never applied for approval or market authorisation? There is no way to know that, unfortunately because of federal confidentiality. One MDVI, LLC was the sponsor of the trial. This company has no/unclaimed website. One mention was found in a list at a website [3]. This is currently the only presence of that company. One manager was named in listed trial details of clinicaltrials.gov. She is Macy Guiont probably of MDVI, LLC; she is not traceable at present. Now another manager is named. She is Carol Epstein of MediVector, Inc. Though primarily MediVector, Inc was collaborator only, they are named now as Sponsor Company in many related news materials [4].

Department of Defence (DOD), USA

In 2014, more than two years after getting a $139 million defence contract to develop a better treatment for the common flu, Boston Biotech Company, MediVector begun two late-stage trials on this that would involve more than 1,000 patients. Fort Belvoir, VA based Department of Defence's (DOD) Joint Program Executive Office for Chemical and Biological defence had one Joint Project Manager of their Transformational Medical Technologies (JPM-TMT). He is David E. Hough. He announced on Oct. 2, 2012 [5], "Our job is to ensure we're making the most out of every dollar we spend".

But unfortunately, this sounds empty words when I diligently followed what happened next to Favipiravir. First in March 15, 2012 his department awarded a $138.5M contract to MediVector, Inc. to further develop Favipiravir (T-705), a broad-spectrum therapeutic against multiple influenza viruses, including the 2009 H1N1 pandemic virus and drug resistant influenza. He told the contract will help bolster the protection of the Joint Forces against naturally occurring pandemic influenza and/or biologically engineered flu viruses. Again, after completion of trial in 2015, MediVector Inc. has been awarded a maximum $9,135,695 modification to previously awarded contract (HDTRA1-12-C-0031) for the capability to manufacture antiviral therapeutic favipiravir in the U.S. The modification brings the total cumulative face value of the contract to $211,303,678 [6].

But after that, there was no FDA approval, no manufacturing, no favipiravir in market and no phase III trial on it targeting COVID-19. It just vanished. Now we see that Tomaya which originally made favipiravir and gave license to MDVI, LLC or MediVector for development III trial. So biggest unanswered question is where had the money gone. One thing intrigued us is how an attempt of Department of defence to develop a drug against atypical influenza in face of bioterrorism completely failed.

CONCLUSION

Present analysis on Favipiravir since its first entry in USA through one or two not-so-famous pharmaceutical company for clinical trial under FDA has shown that its history is shrouded with mystery. Till date there is no explanation from FDA or the company or the Department of defence about the fate of this molecule in USA. This seems to be very important in the context of recent Covid-19 pandemic. State level investigation should be made to know the truth.

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